

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY **WASHINGTON D.C., 20460**

OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

PC Code: 060109 **DP Barcode:** 439307

MEMORANDUM

DATE: November 29, 2017

SUBJECT: Thiamethoxam – Transmittal of the Preliminary Aquatic and Non-Pollinator

Terrestrial Risk Assessment to Support Registration Review

TO: Thomas Harty, Chemical Review Manager

> Ricardo Jones, Team Leader Neil Anderson, Branch Chief

Risk Management and Implementation Branch I Pesticide Re-evaluation Division (7508 P)

FROM: Ryan Mroz, Biologist

Christopher Koper, Chemist

Kristina Garber, Senior Science Advisor

KRISTINA GARBER GARRER CARRER Environmental Risk Branch 1

Environmental Fate and Effects Division (7507 P)

THRU: Sujatha Sankula, Branch Chief

Greg Orrick, Risk Assessment Process Leader

Environmental Risk Branch 1

Environmental Fate and Effects Division (7507 P)

Sankula, Sujatha Sujat

Gate: 2017.11.29 11:11:48 -05700

2017.11.29 13:11:55 -05'00'

This memo transmits the Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to support the Registration Review of Thiamethoxam. This assessment reflects information currently available to the Environmental Protection Agency for assessing the risks of thiamethoxam agricultural and non-agricultural uses to aquatic taxa and non-pollinator terrestrial taxa.

A separate document for assessing risk of clothianidin and thiamethoxam to bees was previously completed (1/5/2017, DP Barcode 437097) and is available in the public docket EPA-HQ-OPP-2011-0865-0173 at www. regulations.gov.

UNITED STATES ENVIRONMENTAL PROTECTION AGENCY WASHINGTON, D.C. 20460



OFFICE OF CHEMICAL SAFETY AND POLLUTION PREVENTION

Preliminary Risk Assessment to Support the Registration Review of Thiamethoxam

Thiamethoxam

IUPAC: 3-(2-Chloro-thiazolyl-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylidene-N-nitroamine

PC code: 060109 CAS: 153719-23-4

November 29, 2017

Prepared by:

Ryan Mroz, Biologist Christopher M. Koper, Chemist Kristina Garber, Senior Science Advisor

Approved by:

Sujatha Sankula, Branch Chief Gregory Orrick, Risk Assessment Process Leader United States Environmental Protection Agency
Office of Pesticide Programs
Environmental Fate and Effects Division
Environmental Risk Branch I
1200 Pennsylvania Ave.
Mail Code 7507P
Washington, D.C. 20460

Contents

1.	Pro	blem	Formulation	10
	1.1.	Regi	istration Review Background	11
	1.2.	Natı	ure of the Chemicals Stressor and Scope of Assessment	11
	1.2	.1.	Overview of Pesticide Usage	11
	1.2	.2.	Pesticide Type, Class and Mode of Action	12
	1.2	.3.	Overview of Physicochemical, Fate, and Transport Properties	12
	1.3.	Ecol	ogical Receptors	13
	1.4.	Ecos	systems Potentially at Risk	13
	1.5.	Asse	essment Endpoints	13
	1.6.	Con	ceptual Model	14
	1.6	.1.	Potential Exposure Routes	14
	1.6	.2.	Risk Hypothesis	14
	1.7.	Ana	lysis Plan	14
	1.7	.1.	Methods of Conducting Ecological Risk Assessment	15
	1.7	.2.	Measures of Exposure	15
	1.7	.3.	Measures of Effect	16
	1.7	.4.	Stressors of Toxicological Concern	17
2.	Exp	osure	Assessment	19
	2.1.	Use	Characterization	19
	2.1	.1.	Thiamethoxam Labeled Use	19
	2.1	.2.	Thiamethoxam Usage	23
	2.1	.3.	Physical, Chemical, Fate and Transport Properties for Thiamethoxam	25
	2.2.	Aqu	atic Exposure Modeling	29
	2.3.	Aqu	atic Exposure Monitoring Data	37
	2.4.	Terr	estrial Exposures	48
	2.4	.1.	Birds and Mammals	48
	2.4	.2.	Terrestrial Plants	51
3.	Ecc	ologica	l Effects Characterization	52
	3.1.	Aqu	atic Organisms (Fish, Aquatic Invertebrates, and Aquatic Plants)	52
	3.1	.1.	Effects on Fish and Aquatic Phase Amphibians	53
	3.1	.2.	Toxicity to Aquatic Invertebrates	54
	3.2.	Effe	cts to Terrestrial Organisms (Birds, Mammals, and Terrestrial Plants)	60
	3.2	.1.	Acute, Sub-Acute, and Chronic Effects on Birds	61
	3.2	.2.	Acute and Chronic Effects on Mammals	63

3.2.	.3.	Terrestrial Plant Toxicity Data	64			
3.3.	Revi	iew of Incident Data	64			
4. Risk	c Char	acterization	66			
4.1.	Risk	Estimation – Integration of Exposure and Effects Data	66			
4.1.	1.	Risk to Fish and Aquatic Phase Amphibians	67			
4.1.	2.	Risk to Aquatic Plants	67			
4.1.	3.	Risk to Aquatic Invertebrates	67			
4.1.	4.	Risk to Birds and Mammals	70			
4.2.	Risk	Description	75			
4.2.	1.	Fish, Aquatic-Phase Amphibians and Aquatic Plants	75			
4.2.	2.	Aquatic Invertebrates	75			
4.2.	3.	Birds	79			
4.2.	4.	Mammals	82			
4.2.	.5.	Terrestrial Plants	83			
4.3.	Ove	rall Conclusions	84			
5. Fed	erally	Threatened and Endangered (Listed) Species Concerns	85			
6. End	locrin	e Disruptor Screening Program	85			
7. Refe	erenc	es Cited	86			
Appendi	Appendix A. Degradates formed in Environmental Fate Studies with Thiamethoxam89					
Appendi	x B. P	WC and PFAM Example Outputs for Thiamethoxam.	95			

Executive Summary

Overview

The purpose of this assessment is to determine potential risks from use of thiamethoxam to aquatic organisms, terrestrial vertebrates (e.g., birds and mammals), and plants. Risks to bees from thiamethoxam agricultural uses were previously evaluated in 2017 (USEPA 2017; DP 437079). An upcoming updated bee risk assessment is scheduled for 2018 encompassing additional data, non-agricultural uses, and public comments. Thiamethoxam is a neonicotinoid insecticide, which acts on the insect nicotinic acetylcholine receptors (nAChRs) of the central nervous system via competitive modulation. The mode of action of thiamethoxam on non-target taxa (e.g., birds, plants) is unknown. Thiamethoxam is in the N-nitroguanidine group of neonicotinoids (IRAC subclass 4A) 1 along with imidacloprid, clothianidin and dinotefuran. Target pests include the chewing and sucking pests such as aphids, whiteflies, thrips, leafhoppers, scales, and leaf miners.

There are currently 80 registered Section 3 end-use products for thiamethoxam. Registered uses include a wide array of agricultural crops, including (but not limited to): root and tuber vegetables, leafy vegetables, brassica, cucurbits, fruiting vegetables, cereal grains, citrus fruit, pome fruit, stone fruit, berries, tree nuts, beans and other legumes, herbs, oilseed crops (e.g., canola, cotton), and tobacco. Thiamethoxam is also registered for several non-agricultural uses, including ornamentals (Christmas trees), turf as well as perimeter/spot treatments.

Applications may be made via a variety of methods including aerial and ground foliar sprays, soil treatment (e.g., drench), chemigation (e.g., soil incorporation or foliar), and as a seed treatment. Maximum single foliar application rates for thiamethoxam range from 0.047-0.266 lb a.i./A. According to the most recent usage reports provided by the Biological and Economic Analysis Division (BEAD) on February 10, 2016 the majority of thiamethoxam used on agricultural crops is applied to soybeans (300,000 lbs/year on seeds), corn (300,000 lbs/year on seeds) and cotton (160,000 lbs/year on seeds and plants). It should be noted that usage data did not account for applications of thiamethoxam to nonagricultural uses.

In this risk assessment aquatic and terrestrial exposure modeling was not conducted for all registered crops/use sites. Rather, the crops/uses modeled were based on several lines of reasoning including: 1) agricultural crops which based on previous risk assessments presented a potential risk to honey bees (i.e., citrus, cotton, cucurbits; USEPA 2017a); 2) representation of major uses for thiamethoxam based on available usage information (i.e., seed treatments); 3) bracket a low and high-end range of estimated environmental concentrations (EECs) (i.e., rice, grapes); 4) representation of non-agricultural registered uses which account for some of the highest application rates (i.e., turf, ornamentals); and 5) grouping uses with similar application rates and scenarios (particularly for the terrestrial exposure component).

For aquatic modeling of foliar and soil applications, the crops modeled are designed to represent the various crop groups (i.e., potatoes represent root and tuber vegetables, tree fruit and nuts represent pome fruit, stone fruit, and tree nuts, turf and ornamental represent non-agricultural uses, forestry represents ornamental shade trees, etc.). Additionally, for seed treatments, sugar beets were modeled

5

¹ http://www.irac-online.org/modes-of-action/

to represent vegetables, wheat to represent all cereal grains, cotton to represent oilseed crops, and the remainder to represent the individual crops for which they are named. While the application rates may not exactly match for the surrogate crop and what they were designed to represent, they were selected to approximate high-end exposures.

Risk Conclusions Summary

The primary risk concerns to aquatic taxa identified in this assessment involve chronic exposures to freshwater aquatic invertebrates (insects in particular). Risks are identified across a variety of use patterns, applying to foliar and soil treatments and to seed treatment on rice. There are also risk concerns for acute exposures to freshwater aquatic invertebrates from use on treated rice seed. Chronic risk concerns for aquatic insects result from exceedances of effect levels on larval survival. Effect levels are also exceeded frequently (10-29 years over a 30-year period) for foliar treatments, suggesting yearly variations (e.g., weather) do not change risk potential. Thiamethoxam concentrations measured in ambient monitoring programs are on the same magnitude as EECs, and also exceed chronic insect toxicity endpoints, supporting the risk conclusions that that environmentally relevant concentrations of thiamethoxam could be sufficient to result in growth impacts to aquatic insects.

The primary risk concerns to terrestrial taxa identified in this assessment involve risks to organisms foraging on thiamethoxam treated seed. Overall, acute risks to non-listed birds and mammals from foliar and soil treatments appear to be low, although a few acute LOC exceedances for listed species and from these use patterns are noted. Dietary intake of thiamethoxam treated seeds result in the highest acute and chronic LOC exceedances from the terrestrial risk assessment to birds and mammals. Larger seeds with lower application rates (e.g. soybean seeds) result in lower potential for risks to both birds and mammals than smaller seeds with higher per seed application rates (e.g. sugar beet seeds).

Potential risks to fish (surrogates for aquatic-phase amphibians) and terrestrial and aquatic plants are anticipated to be low.

The range of risk quotients (RQs) for each taxon is provided in **Table 1**, along with additional lines of evidence.

Environmental Fate and Exposure Summary

Thiamethoxam's primary transport routes from treated sites to non-target areas include spray drift (for foliar applications) and runoff (for all application methods). Thiamethoxam is mobile to moderately mobile in soil (Koc values range 33-178 L/kg-oc) and is soluble (4100 mg/L at 25°C) in water. Volatilization is not considered a major dissipation route based on the vapor pressure (4.95 x 10^{-11} mm Hg) and Henry's Law Constant (4.63 x 10^{-15} atm m³/mol). The n-octanol-water partition coefficient (log Kow = -0.13) for thiamethoxam indicates a low potential for bioaccumulation. In terrestrial habitats, thiamethoxam is persistent, with half-lives on the orders of months (soil photolysis: 2.7-3.2 months; aerobic soil metabolism: 1.1-15.5 months). In aquatic habitats, thiamethoxam is less persistent, with aerobic aquatic metabolism half-lives on the order of weeks (2.3-5.0). In clear or basic water bodies, thiamethoxam may break down more quickly (aqueous photolysis half-lives 3.4-3.9 d; hydrolysis half-lives at pH 9 = 4.2-8.4 d).

Aquatic exposure concentrations were derived considering applications of thiamethoxam alone and did not consider degradation products. Thiamethoxam degrades into clothianidin (PC: 044309), a separate

active ingredient (a.i.) in the neonicotinoid class of chemicals which is subject to its own risk assessment. Assessing risks from exposure of both chemicals was considered; however due to the parent persistence and minimal impact on modeled concentrations (increase of 10^{-2} ppb) and subsequent risk estimations when considering both chemicals clothianidin was not further considered. Additional major degradates of thiamethoxam were also not considered due to a combination of lack of expected toxicity or, like clothianidin, minimal expected impacts on estimated exposure concentrations.

Ecological Effects Summary

On an acute exposure basis, thiamethoxam is very highly toxic (i.e., LC50<100 μ g a.i./L) to aquatic invertebrates. Tested insect species (class Insecta) are more sensitive on an acute exposure basis compared to tested species in other classes (e.g., daphnids and mysid shrimp). By comparison, fish and aquatic plants are several orders of magnitude less sensitive following acute exposure, with LC50 and EC50 values >100,000 and >90,000 μ g a.i./L, respectively. On a chronic exposure basis, a decrease in survival was observed in aquatic insects exposed to 2.23 μ g a.i./L, resulting in a NOAEC of 0.74. As with acute exposure, daphnids and mysid shrimp are orders of magnitude less sensitive when exposed to thiamethoxam on a chronic exposure basis. In the most sensitive fish chronic study, 5% decreased length was observed at 4100 μ g a.i./L (NOAEC = 1.7).

In terrestrial organisms, thiamethoxam is characterized as slightly toxic to birds on an acute oral exposure basis ($LC_{50} = 576$ mg/kg-bw/day) and practically non-toxic on a subacute dietary exposure basis ($LC_{50} > 5200$ mg/kg-diet). Weight loss was seen in a chronic avian reproductive study in parental males at 900 mg/kg-diet (NOAEC 300 mg/kg-diet). The most sensitive avian species is the mallard duck for both acute and chronic exposures. With respect to mammals, thiamethoxam is considered slightly toxic ($LD_{50} = 1563$ mg/kg-bw) on an acute oral basis, and in a chronic exposure reproduction test reduced weight gain was seen in offspring at 158 mg/kg-bw/day (NOAEL 61 mg/kg-bw/day). Generally minimal effects are seen in plant studies; however, some effects on plant height was observed in dicots: oilseed cucumber) IC_{25} and NOAEC 0.28 lb a.i./A and 0.061 lb a.i./A while cucumber IC_{25} and NOAEC values were 0.028 lb a.i./A and <0.017.

Data Gaps/Uncertainties

There are no major gaps related to the environmental fate or toxicity databases. No acceptable data have been submitted to fulfill the requirement for acute oral toxicity data for a passerine species; however, sufficient avian toxicity data are available to complete the risk assessment.

For risks to terrestrial organisms consuming treated seeds, there are several uncertainties with respect to dietary consumption of seeds; notably seeds are available, palatable, consumed as 100% of the diet. These factors can impact risk concerns for foraging birds and mammals; however, due to low estimated numbers of ingested seeds (e.g., corn, cotton, sugarbeet) required to reach levels of concern (LOCs), there are still potential risks to terrestrial animals from consuming treated seeds. Additional consideration is given to seed size where some seeds are considered too large for certain passerine size classes to consume (corn, soybean, and cotton seeds).

All environmental fate data requirements have been fulfilled. This ecological risk assessment was based on maximum labeled application rates and use patterns. To the extent that actual application rates in the field are less than the labeled maximums, actual exposures would be lower. The first application of thiamethoxam was assumed to occur on the 15th day of the wettest month during the typical

application period for thiamethoxam. Depending on the precipitation during other times of the year when thiamethoxam could be applied, EECs could be higher or lower. The EECs for rice were developed using the Pesticide Flooded Application model (PFAM) and reflect exposure concentrations in the paddy. While these levels could potentially occur in a rice paddy and in waterbodies just outside of a release, they are not reflective of waterbodies where complete mixing and dilution have occurred. While monitoring data for thiamethoxam indicated lower levels in surface water than those modelled, the monitoring data may not have been targeted specifically in thiamethoxam use areas or during times of known thiamethoxam use, and as such may not reflect potential peak thiamethoxam concentrations that may occur in surface waters when runoff events occur shortly after application. Adding to this uncertainty, the reporting limits for some of the data has varied over the years or was not reported, so it is uncertain if reported non-detects are instances when thiamethoxam is absent in the waterbody.

Table 1. Summary of Risk Concerns to Taxonomic Groups from Thiamethoxam.

Таха	Exposure Duration	RQ range	RQ Exceeding the LOC?	Additional Information (i.e. Data gaps/ Refinements/ Lines of evidence)
	Acute	PWC: 0.01-0.17; Rice: 0.12-1.9	Yes (rice seed); No (all other uses)	No RQs exceed the non-listed species LOC except use on rice seed, while some RQs for foliar, soil and seed treatment uses exceed listed species LOC for invertebrates in water column.
FW Invertebrates	Chronic	PWC: 0.01-5.1; Rice seed: 5.1-48	Yes	RQs for all modeled foliar and soil uses, except cranberries, exceed the LOC (for both non-listed and listed species) for invertebrates. For seed treatment, only RQs for rice exceed the LOC. RQs are based on insect toxicity data as the most sensitive taxa. The most sensitive toxicological endpoint for insects was reduced survival of larvae. In addition to RQs, other lines of evidence support the risk concerns for aquatic invertebrates. First, EECs for several foliar and soil uses exceed the LOAEC for chronic effects (decreased larval survival). Second, concern levels (NOEC) were exceeded for multiple years of the 30-year simulation for foliar applications to cotton. Third, monitoring data exceed chronic LOAEC value. Risks are not necessarily indicated for all aquatic invertebrates. Non-insect (e.g., waterflea, mysid shrimp) tested species are orders of magnitude less sensitive (such that risk is not indicated). When considering the risk profile for thiamethoxam on the basis of usage, the majority of pounds applied per year is as seed treatments on soybeans, corn and cotton and foliar or soil treatments to cotton. RQs for seed treatment uses on corn, cotton and soybean are below LOCs, indicating low risk for these uses. RQs for foliar applications to cotton are above LOC. It should be noted that because of the seed planting depth>2 cm for corn, EECs and resulting RQs were 0 because seeds were under the assumed run-off zone.
SW	Acute	<0.01	No	None
Invertebrates	Chronic	<0.01	No	None
FW Fish	Acute	<0.01	No	None
I 44 11211	Chronic	<0.01	No	None
SM/ Eich	Acute	<0.01	No	None
SW Fish	Chronic	<0.01	No	None
	Acute	Foliar/Soil: <0.47	No	No RQs exceeded the non-listed LOC for foliar/soil uses

Таха	Exposure Duration	RQ range	RQ Exceeding the LOC?	Additional Information (i.e. Data gaps/ Refinements/ Lines of evidence)
Birds, terrestrial amphibians and reptiles ¹		Seed: 0.06-29.6	Yes	Corn is considered too large for small/med and cotton for small sized passerine consumption; therefore, low risk of passerine dietary exposure. Risk concerns to non-listed species include small/med non-Passeriformes birds for modeled corn and cotton uses, med passerines consuming cotton, and all size classes of birds consuming sugarbeet seeds (or small vegetable seeds). The number of seeds that need to be consumed to reach the non-listed acute LOC for small to large birds: Corn (2-15); Cotton (8-50); Sugar beet (4-368). There are no non-listed exceedances for use on soybean and this seed is also considered too large for passerine consumption.
		Foliar/Soil:<0.19	No	None
	Chronic	Seed: 1.7-117	Yes	Risk concerns are noted for all size classes of birds from all seed treatment uses. Exceptions are noted for small/med passerines potentially consuming corn and soybean seeds and small passerines consuming cotton seeds as these seeds are considered too large to consume by these birds.
		Foliar/Soil: <0.02	No	None
	Acute	Seed: <0.01-2.16	Yes	Acute risk concerns for all size classes uses on small treated vegetable seeds (modeled sugarbeet uses).
Mammals ¹		Foliar/Soil:<0.46	No	None
	Chronic	Seed: 0.36-55.33	Yes	RQs exceed the chronic LOC for all mammalian size classes consuming treated seeds except soybean (no exceedances).
Aquatic plants (vascular)	N/A	<0.01	No	None
Aquatic plants (non- vascular)	N/A	<0.01	No	None
Terrestrial plants (monocots)		NC	No	EC ₂₅ is non-definitive (>); RQs are below the LOC based on a more conservative NOAEC value.
Terrestrial plants (dicots)	N/A	<0.1-4.83	Yes	Two different studies with cucumber produced EC_{25} values of >0.265 and 0.028 (resulting in RQ of 4.8). Risks are unlikely when considering the EC_{25} value of > 0.265 lb a.i./A (results in RQ <0.1) and when considering minimal plant effects seen in these studies.

¹ RQs and risk conclusions are based on a dietary exposure route.

RQ=risk quotient; N/A=not applicable; NC=not calculated; FW = Freshwater; SW = Saltwater;

Chronic risk LOC = 1.0 for terrestrial animals; Acute risk LOC for non-listed terrestrial species = 0.5; Acute risk LOC for non-listed aquatic animals = 0.5; Aquatic and terrestrial plant risk LOC = 1.0.

1. Problem Formulation

The problem formulation serves as the first step of a risk assessment and it provides the foundation for the entire ecological risk assessment. In addition to identifying the risk assessment scope and objectives, the problem formulation includes three major components: (1) assessment and measurement endpoints that reflect management goals and the ecosystem they represent, (2) conceptual models that describe key relationships between a stressor (i.e., pesticide) and assessment endpoint or between several stressors and assessment endpoints, and (3) an analysis plan that summarizes the key sources of data and methods to be used in the risk assessment (USEPA 1998).

1.1. Registration Review Background

As articulated by the Agency's Registration Review Schedule, the nitroguanidine-substituted neonicotinoid insecticides (imidacloprid, clothianidin, thiamethoxam, dinotefuran) are currently undergoing Registration Review². The first installment of the Registration Review process for thiamethoxam was the publication of the Problem Formulation and Preliminary Work Plan documents in 2011, (USEPA 2011a, 2011b). These documents summarized the available data on ecological effects and environmental fate of thiamethoxam, identified key data gaps, and set forth a schedule for obtaining these data and completing the ecological risk assessment. Following its receipt and response to public comments, the Agency published a Final Work Plan in 2012 (USEPA 2012). In 2013, a Generic Data Call-In (GDCI) was issued (USEPA 2013) that required registrants to submit certain types of environmental fate and effects data in preparation for the forthcoming Preliminary Ecological Risk Assessment document. In January 2017, EPA completed a risk assessment focused on the risks of thiamethoxam to bees applied to agricultural sites (USEPA 2017). An updated bee risk assessment is anticipated to be published in 2018 to include additional data received, non-agricultural uses, and incorporating any relevant comments received (e.g., during the public comment period).

1.2. Nature of the Chemicals Stressor and Scope of Assessment

The focus of this Preliminary Ecological Risk Assessment is on the risk of registered agricultural and non-agricultural thiamethoxam uses to aquatic organisms, specifically fish, invertebrates and plants, as well as for birds, mammals and terrestrial and wetland plants. This assessment utilizes an approach producing quantitative assessments from several representative crop use patterns to bridge or cover risk conclusions to the aforementioned taxon groups for all registered uses. Both the aquatic and terrestrial exposure and effects assessments will model similar use patterns to be protective of all uses based on crop usage data, application type, and application rates. Further characterization is added where necessary if the use patterns modeled are expected to be over or under protective.

1.2.1. Overview of Pesticide Usage

Thiamethoxam may be applied to crops via a variety of methods including aerial and ground foliar sprays, soil treatment (e.g., drench), chemigation (e.g., soil incorporation or foliar), and as a seed treatment. Thiamethoxam is used on a wide array of agricultural crops, including (but not limited to): root and tuber vegetables, leafy vegetables, brassica, cucurbits, fruiting vegetables, cereal grains, citrus fruit, pome fruit, stone fruit, berries, tree nuts, beans and other legumes, herbs, oilseed crops (e.g., canola, cotton), and tobacco. There are also a wide variety of non-agricultural uses of thiamethoxam,

² Thiamethoxam docket can be found at: https://www.regulations.gov/docket?D=EPA-HQ-OPP-2011-0581

including turf, lawns and ornamentals³. There are currently 80 registered Section 3 end-use products for thiamethoxam and 3 technical/manufacturing product labels. For agricultural uses, the maximum single application rates allowed for thiamethoxam are 0.09 lb a.i./A (pounds of active ingredient per acre) for foliar application and 0.266 lb a.i./A for soil applications. Seed treatment applications are variable based on seed size and seeding rate, but these are such that the maximum amount of a.i/A should not exceed 0.266 lb a.i./A. The turf and non-agricultural uses on ornamentals application rates are in line with application rates for agricultural uses, not exceeding 0.266 lb a.i./A. A detailed summary of registered agricultural and non-agricultural uses of thiamethoxam to be included in this assessment is provided in Section 2.1.1 and this is adapted from the details in the stand alone problem formulation document (USEPA 2011a).

1.2.2. Pesticide Type, Class and Mode of Action

Thiamethoxam (IUPAC name: (3-(2-Chloro-thiazolyl-5-ylmethyl)-5-methyl- [1,3,5]oxadiazinan-4-ylidene-N-nitroamine)) is a systemic, neonicotinoid insecticide which acts on the insect nicotinic acetylcholine receptors (nAChRs) of the central nervous system via competitive modulation (IRAC 2015). Thiamethoxam is in the N-nitroguanidine group of neonicotinoids (IRAC subclass 4A) along with imidacloprid, clothianidin, and dinotefuran. The mode of action on target insects (terrestrial and aquatic) involves out-competing the neurotransmitter, acetylcholine for available binding sites on the nAChRs (Zhang *et al.* 2008). At low concentrations, neonicotinoids cause excessive nervous stimulation and at higher concentrations, insect paralysis and death will occur (Tomizawa and Casida 2005). Thiamethoxam is systemic; as such, it kills feeding insects via ingestion or direct contact routes of exposure. Target pests include the chewing and sucking pests such as aphids, whiteflies, thrips, leafhoppers, scales, and leaf miners.

1.2.3. Overview of Physicochemical, Fate, and Transport Properties

Section 2.1.3 provides a detailed discussion of the physicochemical, fate, and transport properties of thiamethoxam. Briefly, thiamethoxam is a water soluble chemical with low vapor pressure and Henry's Law Constants. These properties suggest that the chemical will be readily soluble for movement with water and that it is unlikely to volatilize to a meaningful degree. The organic carbon partition coefficient (Koc) values indicate thiamethoxam is mobile to moderately mobile in soil. In addition, the organic carbon: water partitioning coefficient (K_{ow}) for thiamethoxam is low which suggests it is unlikely to bioaccumulate in living tissues. The major routes transporting thiamethoxam from treatment sites to off-site habitats include runoff and spray drift.

The dominant transformation process for thiamethoxam is photolysis (days in water; months in soil). Aerobic soil transformation is slow (half-life values are on the order of months to more than a year) and therefore, thiamethoxam is expected to persist in the soil system. Photodegradation may occur on soil surfaces following soil application and on wet foliage in the case of foliar application; photolysis on dry soil appears to be slower. In plants, thiamethoxam may be taken up via the roots or across plant stems and leaves. Thiamethoxam is considered xylem mobile, with dominant uptake routes following the

³ Other non-agricultural uses include indoor and outdoor uses that were either baits, spot treatments, void treatments, crack or crevice treatments, perimeter treatments, or wood protection treatment by pressure. Wood protection products are evaluated in EFED's registration review ecological risk assessment; these antimicrobial uses will be evaluated by the Antimicrobial Division

⁴ http://www.irac-online.org/

transpiration stream (i.e., no downward transport from leaves to roots). Although xylem mobile, numerous field studies have demonstrated thiamethoxam applied via foliar, soil or seed treatment methods can result in residues in pollen and nectar of blooming plants indicating it is phloem mobile as well, and available data suggest that thiamethoxam is metabolized within plants to form clothianidin.

1.3. Ecological Receptors

The receptor is the biological entity that is exposed to the stressor (US EPA, 1998). As indicated previously, this assessment focuses on all ecological taxa, excluding terrestrial invertebrates. Accordingly, aquatic receptors potentially at risk include (but are not limited to): invertebrates (e.g., aquatic insects, mollusks, crustaceans, and worms) as well as fish, amphibians, and vascular/non-vascular plants. While terrestrial receptors include birds, mammals, and plants. Birds are also used as surrogates for terrestrial-phase amphibians and reptiles. Bees were assessed in a separate document (USEPA 2017a).

Consistent with the process described in the Overview Document (US EPA, 2004), this risk assessment uses the surrogate species approach in its evaluation of thiamethoxam. Toxicological data generated from surrogate test species, that are intended to be representative of broad taxonomic groups, are used to extrapolate to potential effects on a variety of species (receptors) among these taxonomic groupings.

Acute and chronic toxicity data from studies submitted by pesticide registrants along with data from the available open literature are used to evaluate potential direct effects of thiamethoxam to the aquatic and terrestrial receptors identified in this section. The open literature studies are identified through EPA's ECOTOX database (http://cfpub.epa.gov/ecotox/), which employs a literature search engine for locating chemical toxicity data for aquatic life, terrestrial plants, and wildlife.

1.4. Ecosystems Potentially at Risk

The ecosystems at potential risk from thiamethoxam are extensive in scope due to the wide geographic distribution of potential thiamethoxam application sites. Aquatic ecosystems potentially at risk include water bodies adjacent to (or downstream from) the treatment area and might include: static water bodies such as ponds, lakes, and wetland areas, impounded water bodies such as reservoirs or flowing waterways such as streams and rivers. For uses in coastal areas, aquatic habitat also includes marine ecosystems, including estuaries and salt marshes. Terrestrial ecosystems potentially at risk could include the treated area and immediately adjacent areas that may receive drift or runoff. Areas adjacent to the treated area could include cultivated fields, fencerows and hedgerows, meadows, fallow fields or grasslands, woodlands, riparian habitats and other uncultivated areas.

1.5. Assessment Endpoints

Assessment endpoints represent the actual environmental value that is to be protected, defined by an ecological entity (species, community, or other entity) and its attribute or characteristics (US EPA, 1998). For thiamethoxam, the ecological entities may include the following: aquatic animals (freshwater and estuarine/marine fish and invertebrates) and terrestrial animals (birds and mammals). The attributes for each of these entities may include growth, reproduction, and survival and are discussed further in Sections 2.7 and 3 (Ecological Effects Characterization).

1.6. Conceptual Model

For a pesticide to pose an ecological risk, it must reach ecological receptors in biologically significant concentrations. An exposure pathway is the means by which a pesticide moves in the environment from a source to an ecological receptor. For an ecological pathway to be complete, it must have a source, a release mechanism, an environmental transport medium, a point of exposure for ecological receptors, and a feasible route of exposure. A conceptual model is used in this risk assessment to provide a written and visual description of the predicted relationships between thiamethoxam, potential routes of exposure, and the predicted effects for the assessment endpoint. A conceptual model consists of two major components: risk hypotheses and a conceptual diagram (US EPA, 1998).

1.6.1. Potential Exposure Routes

Based on the preliminary iterative process of examining fate and effects data, the conceptual model from the 2011 problem formulation for the risk hypothesis model for foliar spray, soil, and seed treatment application is referenced (USEPA 2011a) and identifies: (1) likely stressors/exposure pathways and (2) organisms that are most relevant and applicable to this assessment. Primary exposure routes for aquatic organisms include spray drift and runoff of thiamethoxam into nearby bodies of water. Once in the water, the primary exposure route to aquatic organisms is direct uptake across respiratory membranes. For terrestrial animals, the major route of exposure is via diet, such as through consumption of plant leaves or insects, which contain thiamethoxam residues as a result of direct application and/or spray drift. However, exposure from inhalation of spray droplets and from ingestion of contaminated drinking water is also considered. The potential for thiamethoxam to bioaccumulate in living tissues is determined to be low based on its log K_{OW}.

1.6.2. Risk Hypothesis

Risk hypotheses are specific assumptions about potential adverse effects (*i.e.*, changes in assessment endpoints) and may be based on theory and logic, empirical data, mathematical models, or probability models (EPA 1998). The ensuing risk assessment will evaluate whether or not the specific risk hypotheses are supported. For foliar, soil, and seed treatment applications of thiamethoxam, the following ecological risk hypothesis is being employed for this risk assessment:

Based on the environmental fate, specifically the solubility, mobility, and persistence of thiamethoxam as well as its broad range of registered uses and application methods, there is a potential that aquatic and terrestrial organisms will be exposed when thiamethoxam is used in accordance with the label. Consequently, considering the MOA and toxicity of thiamethoxam, the registered uses have the potential to cause adverse effects upon the survival, growth, and reproduction of non-target aquatic and terrestrial organisms.

1.7. Analysis Plan

The analysis plan provides a rationale for selecting and omitting risk hypotheses in the risk assessment. As with any risk assessment process, the analysis plan also articulates data gaps, the methods used to evaluate existing and anticipated data, and the assumptions that will be made where data may be missing. The analysis plan also identifies the specific measures of exposure (e.g., estimated

environmental concentrations; EECs) and effect (e.g., median lethal dose for 50% of the organisms tested; LD₅₀) which will be used to develop risk quotients.

1.7.1. Methods of Conducting Ecological Risk Assessment

The primary method used to assess risk in this preliminary assessment is the risk quotient (RQ) and follows closely methods outlined in the EPA Overview Document (USEPA, 2004). The RQ is the risk value for this preliminary assessment and is the result of comparing measures of exposure to measures of effect. A commonly used measure of exposure is the estimated exposure concentration (EEC) and commonly used measures of effect include toxicity values such as the median lethal dose to 50% of the organisms tested (LD₅₀), medial lethal concentration to 50% of tested organisms (LC₅₀), the no observed adverse effect level (NOAEL)⁵, and the no observed adverse effect concentration (NOAEC). The resulting ratio of the point estimate of exposure and the point estimate of toxicity, *i.e.*, the RQ, is then compared to a specified level of concern (LOC), which represents a threshold for concern; if the RQ exceeds the LOC, risks concerns are triggered. Risk presumptions, along with the corresponding RQs, equations, and LOCs are summarized in **Section 4**. Generation of robust RQs is dependent on the quality of data from both fate and toxicological studies. The adequacy of the submitted data was evaluated relative to Agency guidelines.

1.7.2. Measures of Exposure

Measures of exposure are estimates for a receptor that can be determined by modeling or monitoring data. Measures of exposure for thiamethoxam are obtained from both modeling and available monitoring data.

Estimated environmental concentrations (EECs) in aquatic habitats were generated using EFED's standard tools, the Pesticide in Water Calculator (PWC) graphical user interface (GUI) which integrates the Pesticide Root Zone Model (PRZM5) and the Variable Volume Water Model (VVWM) and the Pesticide Flooded Application Method (PFAM; Version 2) model for rice and cranberry applications to estimate aquatic exposure concentrations⁶. PWC estimates pesticide movement and transformation on an agricultural field and in the receiving surface water body (*i.e.*, EPA standard pond), for terrestrial use sites and PFAM was developed specifically to estimate exposure for pesticides used in flooded agriculture such as rice paddies. PFAM was also used to estimate exposure for a periodic flooded cranberry bog and wet-harvest of cranberry.

Terrestrial wildlife is potentially exposed to thiamethoxam via consumption of residues on food items. For spray applications, the T-REX model (Terrestrial Residue EXposure model; v. 1.5.2; June 6, 2013b) is used to predict dietary exposure to thiamethoxam residues on foliar surfaces and insects using the Kenaga nomogram as modified by Fletcher (Hoerger and Kenaga 1972, Fletcher *et al.* 1994). In this assessment, a default foliar dissipation half-life of 35 days is used for terrestrial modeling purposes since suitable foliar dissipation data specific to thiamethoxam are not available. For soil treatments the LD_{50}/ft^2 methodology using default assumptions about incorporation (0%) as well as residues on arthropod dietary times in T-REX are used to estimate exposure from treated soil. For seed treatments, T-REX is also used to assess exposures and associated risks to granivore birds and mammals. In areas

⁵ A NOAEL refers to a dose-based toxicity endpoint whereas a NOAEC refers to a concentration based endpoint.

⁶ www.epa.gov/pesticide-science-and-assessing-pesticide-risks/models-pesticide-risk-assessment

where risks are identified, refinements are made based on EFED's interim guidance on assessing risks through seed treatments. The model used to derive EECs and RQs relevant to terrestrial and wetland plants is TerrPlant (v.1.2.2; 10/29/2009). The AgDRIFT spray drift model (v2.1.1) is used to assess exposures of organisms to thiamethoxam deposited by spray drift onto areas adjacent to the treated field/orchard.

1.7.3. Measures of Effect

Measures of ecological effects are obtained from a suite of registrant-submitted guideline studies conducted with a limited number of surrogate species. The test species are not intended to be representative of the most sensitive species but rather were selected based on their ability to thrive under laboratory conditions. Measures of effect are based on deleterious changes in an organism as a result of chemical exposure. Functionally, measures of effect typically used in risk assessments include changes in survival, reproduction, or growth as determined from standard laboratory toxicity tests. The focus on these effects for quantitative risk assessment is due to their clear relationship to higher-order ecological systems such as populations, communities, and ecosystems. Monitoring data such as adverse effect incident reports may also be used to provide supporting lines of evidence for the risk characterization.

In addition, effects other than survival, reproduction, and growth may be considered, though rarely are they used quantitatively to estimate risks since, in many cases, the relationship between these effects and higher-order processes is undefined. Commonly used laboratory-derived toxicity values include estimates of acute mortality (e.g., LD_{50} , LC_{50}) and estimates of effects due to longer term, chronic exposures (e.g., NOAEC, NOAEL). The latter can reflect changes seen in mortality, reproduction, or growth. In general, for a given assessment endpoint the lowest (i.e., most sensitive) relevant measure of effect is used in calculating the RQ. Assessment endpoints and their respective measures of effect are listed in **Table 2**.

Table 2. Summary of Assessment and Measurement Endpoints used in this assessment

Assessment Endpoint	Measures of Exposure	Measures of Effect
1. Survival and reproduction of	1-d EEC (acute), 21-d &	1a. Most sensitive freshwater fish acute
individuals and communities of	60-d surface water EEC	LC ₅₀ .
freshwater fish ² and	(chronic) ¹	1b. Most sensitive freshwater fish early
invertebrates.		life stage chronic NOAEC and LOAEC.
		1c. Most sensitive freshwater
		invertebrate acute EC ₅₀ /LC ₅₀ .
		1d. Most sensitive freshwater
		invertebrate chronic reproduction NOAEC
		and LOAEC.
2. Survival and reproduction of	1-d EEC (acute), 21-d &	2a. Most sensitive estuarine/marine fish
individuals and communities of	60-d surface water EEC	acute LC ₅₀ .
estuarine/marine fish and	(chronic) ¹	2b. Most sensitive estuarine/marine fish
invertebrates.		early life stage chronic NOAEC and LOAEC.
		2c. Most sensitive estuarine/marine
		invertebrate acute EC ₅₀ /LC ₅₀ .
		2d. Most sensitive estuarine/marine
		invertebrate chronic reproduction NOAEC
		and LOAEC.

Assessment Endpoint	Measures of Exposure	Measures of Effect
3. Growth of aquatic plants	1-d EEC ¹	3a. Most sensitive non-vascular plant EC ₅₀
		3b. NOAEC or EC ₀₅ associated with species
		tested in 3a.
		3c. Most sensitive vascular plant EC ₅₀
		3d. NOAEC or EC ₀₅ associated with species
		tested in 3c.
4. Survival and reproduction of	Peak EEC	4a. Most sensitive avian acute LD ₅₀ (dose-
individuals and communities of		based).
birds ³ and mammals.		4b. Most sensitive avian acute LC ₅₀
		(dietary-based).
		4c. Most sensitive avian chronic
		reproduction NOAEC and LOAEC.
		4d. Most sensitive mammalian LD ₅₀ .
		4e. Most sensitive mammalian (rat)
		chronic reproduction NOAEC/NOAEL and
		LOAEC/LOAEL.
5. Growth of terrestrial and	Peak runoff + drift EEC	5a. Most sensitive dicot plant EC ₅₀ from
wetland plants		seedling emergence test
		5b. NOAEC or EC ₀₅ associated with species
		tested in 5a.
		5c. Most sensitive monocot plant EC ₅₀
		from seedling emergence test
		5d. NOAEC or EC ₀₅ associated with species
		tested in 5c.
6. Growth of terrestrial and	Drift EEC	6a. Most sensitive dicot plant EC ₅₀ from
wetland plants		seedling emergence or vegetative vigor
		test
		6b. NOAEC or EC ₀₅ associated with species
		tested in 6a.
		6c. Most sensitive monocot plant EC ₅₀
		from seedling emergence or vegetative
		vigor test
		6d. NOAEC or EC ₀₅ associated with species
		tested in 6c.

 LD_{50} = Lethal dose to 50% of the test population; NOAEC = No-observed-adverse-effect level; LOAEC = Lowest-observed-adverse-effect level; LC_{50} = Lethal concentration to 50% of the test population; EC_{50} = Effect concentration to 50% of the test population.

1.7.4. Stressors of Toxicological Concern

As will be discussed in Section 2.1.3, thiamethoxam may degrade into various compounds through multiple pathways. One of thiamethoxam's degradation products is clothianidin (PC code 044309; also referred to as CGA-322704), which is also a registered neonicotinoid insecticide. In the majority of the available fate studies, clothianidin is formed as a minor degradate (<10% of the applied dose); however, it was identified as a major degradate (>10% of applied residue) in four of eight aerobic soil metabolism

¹ Based on a 1-in-10-year return frequency.

² In the absence of data, freshwater fish may be used as surrogates for aquatic-phase amphibians in accordance with EFED risk assessment guidance.

³ In the absence of data, birds may be used as surrogates for terrestrial-phase amphibians and reptiles in accordance with EFED risk assessment guidance.

studies (18.9%,23.7%, 29.4%, 36.8%), one of two anaerobic soil metabolism studies (17.3%) as well as one of seven field dissipation studies (13.2%).

To evaluate how clothianidin formation may affect aquatic exposure concentrations, a total residue (thiamethoxam + clothianidin) approach was modeled based on the aerobic soil metabolism input parameter (only) as anaerobic soil metabolism and field dissipation studies do not contribute to model inputs. This changed the parent (thiamethoxam) only aerobic soil metabolism model half-life input (236 days) to stable. Comparison of the thiamethoxam versus the total residue model runs showed that the largest increase in acute aquatic exposure was 0.12 ppb which does not change the current risk estimations and conclusions based on a thiamethoxam only modeled exposure. Furthermore, clothianidin is currently being assessed at rates higher than what would be expected from clothianidin formation through thiamethoxam degradation (0.10 lb a.i/A)⁷, therefore, EECs used for this risk assessment are for parent thiamethoxam only.

Several other compounds were also identified as major degradate in most of the available fate studies including: CGA-353042, CGA-335190, NOA-404617 and NOA-407475. When considering degradates of potential toxicological concern, it is assumed that the toxicity associated with thiamethoxam is attributed to the presence of the N-nitro group. Of the major degradates, only NOA-404617 maintains the N-nitro group, so, CGA-353042, CGA-335190, and NOA-407475 are assumed to be less toxic than the parent. The metabolite NOA-404617 was formed through hydrolysis under alkaline conditions (pH 9) (which is not accounted for in aquatic modeling) and in one aerobic aquatic metabolism study (where the half-life of thiamethoxam is already on the order of months). When the aerobic aquatic metabolism half-life is assumed to be stable, aquatic exposure 1-d, 21-d and 60-d EECs increase by as much as a factor of 2.8, 3.2 and 4.6 respectively, indicating little influence on EECs. Therefore, NOA-404617 was not included quantitatively in the EECs.

While both chemicals show a similar toxicity to fish, clothianidin shows greater toxicity to aquatic invertebrates than the parent thiamethoxam and similar toxicity to terrestrial organisms (USEPA 2017b). However, all neonicotinoid insecticides are expected to exhibit a high toxicity to aquatic invertebrates, particularly insect larvae, in part due to the mode of action. Clothianidin was not formed in available aerobic aquatic metabolism studies and was formed at less than 3.8% in an anaerobic aquatic metabolism study. Due to low formation in the aquatic environment and already expected high toxicity to aquatic insects (parent), risk conclusions are not expected to significantly be changed by considering toxicity of both the parent thiamethoxam and clothianidin. Consequently, for aquatic organisms the parent thiamethoxam is considered the stressor of concern in this assessment.

As discussed in the bee risk assessment conducted for thiamethoxam and clothianidin (USEPA 2017), both thiamethoxam and clothianidin have been observed in plant tissues following applications of thiamethoxam via foliar, soil, and seed treatments. For terrestrial vertebrate risk assessments, the stressor of concern is thiamethoxam alone because 1) exposure is assessed based on peak applications of thiamethoxam (highly influenced by the day of application and less influenced by degradation), 2) a default foliar dissipation half-life of 35 d is used, and 3) thiamethoxam and clothianidin exhibit similar

Review Committee (MARC) suggested that the toxicity associated with thiamethoxam was due to the presence of the N-nitro group (USEPA, 1999).

 $^{^{7}}$ Highest estimated application rate for clothianidin in this assessment: = highest thiamethoxam application rate (0.266 lb a.i/A) x maximum clothianidin formation (0.368) = 0.10 lb a.i/A

⁸ The Metabolism Assessment

toxicity to birds, mammals, and plants. Both chemicals are systemic (i.e. translocated into plant materials from seed, soil, or foliar application) and there is an acknowledged uncertainty with respect to exposure of foraging birds and mammals to both thiamethoxam and clothianidin in treated plant materials; however, risk conclusions are not expected to be significantly altered for terrestrial organisms.

2. Exposure Assessment

2.1. Use Characterization

Exposure assessment for the registered uses of thiamethoxam begins with a detailed characterization of its labeled uses and current data on its usage across all crops (Section 2.1). Information regarding the fate and transport of thiamethoxam and its transformation products is also evaluated (Section 2.1.3). The labeled uses combined with environmental fate parameters serve as key inputs to the aquatic exposure modeling (Section 2.2). In addition to modeled concentrations, available data on concentrations of thiamethoxam measured in surface waters of the U.S. is also considered and evaluated (Section 2.3).

2.1.1. Thiamethoxam Labeled Use

Thiamethoxam may be applied to crops via a variety of methods including aerial and ground foliar sprays, soil treatment (e.g., drench), chemigation (e.g., soil incorporation or foliar), and as a seed treatment. Thiamethoxam is used on a wide array of agricultural crops, including (but not limited to): root and tuber vegetables, leafy vegetables, brassica, cucurbits, fruiting vegetables, cereal grains, citrus fruit, pome fruit, stone fruit, berries, tree nuts, beans and other legumes, herbs, oilseed crops (e.g., canola, cotton), and tobacco. Additionally, there are non-agricultural uses including application to turf, ornamentals, and other spot/perimeter treatments⁹. There are currently 80 registered Section 3 enduse products for thiamethoxam.

Maximum single foliar and soil application rates allowed for thiamethoxam range from 0.05 to 0.265 lb a.i./A (pounds of active ingredient per acre) for most crops (**Table 3 and Table 4**). Thiamethoxam is also registered for use as a seed treatment on many crops (**Table 5**). In general, for the seed treatments, labels indicate that regardless of application method [e.g., application/seeding rate], to not apply more than 0.265 lb a.i./A/year. Where the table indicates "all registered uses" this language is intended to include the set or subset of actual registered crops within a crop group. It does not mean that all crops are registered for thiamethoxam within that crop group. The maximum application rates for non-agricultural uses is 0.265 lb a.i./A.

Table 3. Maximum rates for foliar applications of thiamethoxam

.

⁹ Airports/landing fields, animal housing premises (indoor/outdoor), commercial/institutional industrial premises/equipment, commercial storages/warehouses premises, commercial transportation facilities, household/domestic dwellings, poultry feedlots, ships and boats, wood pressure treatment to forest products, wood protection treatment to buildings/products. Applications include both indoor and outdoor uses that were either baits, spot treatments, void treatments, crack or crevice treatments, perimeter treatments.

Thiamethoxam				
Use	Max Single app rate (lb a.i./A)	# of apps	App. interval (d)	Method
	AGRICULTURAL			.
Ci	op Group 1 – Root and Tuber Vegetable	S		
Root and tuber vegetables, Crop Group 1 – Except listed below	0.05	2	7	a, g
Crop Subgroup 1A. Tuberous and corm vegetables subgroup: Sugar beet	0.05	2	7	a, g
Crop Subgroup 1b. Tuberous and corm vegetables subgroup (except sugar beet): Except listed below	0.063	2	7	a, g
Radish	0.063	1	N/A	a, g
Crop Subgroup 1C. Tuberous and corm vegetables subgroup: Potato	0.05	2	7	a, c, g
Crop Group	4 – Leafy Vegetables (Except brassica V	egetables)	•	
All registered uses	0.088	2	7	a, g
Crop	Group 5 – Brassica (Cole) Leafy Vegetal	bles		-
All registered uses	0.088	2	7	a, g
Crop Gr	oup 6 - Legume Vegetables (Succulent o	r Dried)		-
Soybeans	0.063	2	7	a, g
Crop G	oup 8 – Fruiting Vegetables (Except Cuc	urbits)		-
All registered uses	0.088	2	7	a, g
	Crop Group 9 – Cucurbit Vegetables			-
All registered uses	0.088	2	5	a, g
	Crop Group 11 – Pome Fruits			-
All registered uses – Except listed below	0.086	3	10	g
Apple	0.071 (pre bloom)	3	10	g
	Crop Group 12 – Stone Fruits			•
All registered uses	0.088	2	10	g
	Crop Group 13-07 – Berry and Small Fruit	-	,	
Crop Subgroup 13-07A. Caneberry Subgroup.	0.047	2	7	a, g
Crop Subgroup 13-07B. Bushberry Subgroup.	0.063	2	7	a, g
Crop Subgroup 13-07G. Low growing berries	0.063	3	10	g
Crop Subgroup 13-07H. Low growing berry subgroup, except strawberry. Cranberry	0.063	2	7	c, g
Crop Subgroup 13-07D. Small fruit vine climbing subgroup.	0.055	2	14	a, g

	Thiamethoxam				
Use	Max Single app rate (lb a.i./A)	# of apps	App. interval (d)	Method	
Crop Subgroup 13-07E. Small fruit					
vine climbing subgroup, except					
grape. Vine fruits					
Crop Subgroup 13-07F. Small fruit					
vine climbing subgroup except	0.056	2	14	a, g	
fuzzy kiwifruit. Grapes					
	Crop Group 14 – Tree nuts				
All registered uses	0.063	2	7	a, g	
	Crop Group 15 – Cereal Grains				
Barley	0.063	2	7	a, g	
1	Crop Group 19 – Herbs and Spices		1	•	
Mint	0.063	3	14	a, g	
	Crop Group 20 – Oilseed		1	J	
Cotton	0.063	2	5	a, g	
Crop Group 2.	3 – Tropical and Subtropical Fruit, Edibl	e Peel Grou	p		
All registered uses	0.063	3	7	a, g	
Crop Group 24	– Tropical and Subtropical Fruit, Inedib	le Peel Gro	up	1	
All registered uses	0.063	3	7	a, g	
	Other Crops		1	1	
Artichoke	0.047	2	7	a, g	
Tobacco	0.05	2	3	a, g	
	NON-AGRICULTURAL				
Turf	0.266	(1)	NS	g	
Ornamentals	0.266	(1)	7	g	

NS = Not Specified; NA = not applicable; g= ground; a= aerial; c=chemigation; () = assumed based on max labeled rate

Table 4. Maximum application rates for soil applications of thiamethoxam

	Thiamethoxam				
Use	Single app rate (lb a.i./A	# of apps	App.		
	Crop Group 1 – Root and Tuber Vegetables				
All registered uses – Except listed below	0.18	1			
Radish	0.1	1			
Crop subgroup 1-C. Tuberous and corm vegetables	0.13	1			
Crop Grou	p 4 - Leafy Vegetables (Except Brassica Veg	etables)	1		
All registered uses	0.17	1			
Crop :	Subgroup 5-B - Brassica Leafy Greens Subgr	oup	,		
All registered uses	0.1	1			
	Crop Subgroup 8-10 – Fruiting Vegetables	•			

	Thiamethoxam				
Use	Single app rate (lb a.i./A	# of apps	App.		
All registered uses	0.17	1			
	Crop Group 9 - Cucurbit Vegetables				
All registered uses	0.17	1			
	Crop Group 10 – Citrus				
Citrus (FL)	0.17	1			
	Crop Group 13-07 — Berry and Small Fruit				
below Crop Subgroup 13-07G. Low growing berries (except cranberry) Strawberry	0.19 (0.16)	1			
Crop Subgroup 13-07F. Small fruit vine climbing subgroup except fuzzy kiwifruit. Grapes	0.27 (0.2)	1			
	NON-AGRICULTURAL				
Turf	0.266	(1)	NS		
Ornamentals	0.266	(1)	7		

NS = not specified; () = assumed based on max labeled rate

Table 5. Seed treatment uses and corresponding application rates registered for thiamethoxam.

Use	Thiamethoxam		
USE	lb a.i./seed	lb a.i./lb seed	
Croj	o Group 1 – Root and Tuber Vege	etables	
Carrot	1.1E-07	NA	
Potato	NA	6.2E-05	
Sugar Beet	1.6E-06	NA	
	Crop Group 3 – Bulb Vegetable	s	
Onion (including scallions, leeks and spring)	4.4E-07	NA	
Crop Group 4	– Leafy Vegetables (Except bras	sica Vegetables)	
Leafy vegetables (Except Brassica), Crop Group 4	2.7E-06	NA	
Amaranth, Chinese	2.7E-06	NA	
Lettuce	1.3E-07	NA	
Spinach	2.7E-07	NA	
Corn salad	2.7E-06	NA	
Crop G	Group 5 – Brassica (Cole) Leafy Ve	egetables	
Brassica leafy vegetables, Crop Group 5	2.2E-07	NA	
	Crop Group 6- Legume vegetabl	es	

Use	Thiamethoxam		
Use	lb a.i./seed	lb a.i./lb seed	
Legume vegetables, Crop Group 6	NA	5.0E-04	
Beans	NA	5.0E-04	
Soybeans	NA	7.5E-04	
Lentils	NA	5.0E-04	
Peas	NA	2.5E-04	
'	Crop Group 9 - Cucurbit vegetabl	les es	
Cucurbit vegetables, Crop Group 9	1.7E-06	NA	
,	Crop Group 15 – Cereal Grains		
Cereal grains	NA	5.2E-04	
Barley	NA	5.2E-04	
Buckwheat	NA	5.2E-04	
Corn (unspecified)	2.8E-06	NA	
Corn (field)	1.3E-06	9.9E-04	
Corn (pop)	1.3E-06	2.2E-03	
Corn (sweet)	1.3E-06	1.8E-03	
Millet	NA	5.2E-04	
Oat	NA	5.2E-04	
Rice	7.0E-08	NA NA	
Rye	NA	5.2E-04	
Sorghum	NA	3.0E-03	
Teosinte	NA	5.2E-04	
Triticale	NA	5.2E-04	
Wheat	NA	5.2E-04	
	Crop Group 20 - Oilseed		
Entire Group – Except listed below	NA	4.0E-03	
Canola	NA	4.0E-03	
Cotton	8.3E-07	NA	
Sunflower	5.5E-07	NA	
	on-grass Animal Feeds (Forage Fo	***************************************	
Alfalfa	1.1E-06	NA NA	
	Other Crops		
Peanuts	6.4E-07	4.5E-04	

NA = not applicable

2.1.2. Thiamethoxam Usage

According to the most recent usage report provided by the Biological and Economic Analysis Division (BEAD) (thiamethoxam Screening Level Usage Analysis (SLUA) dated 2/10/16), the majority (approximately 80%) of thiamethoxam used on agricultural crops is applied to soybeans (300,000 lbs/year on seeds), corn (300,000 lbs/year on seeds) and cotton (160,000 lbs/year on seeds and plants). For corn, an estimated annual average of 25% total crop is treated with thiamethoxam (maximum of 45% for thiamethoxam in any given year). Current thiamethoxam end-use product labels restrict use on corn to seed treatment only. Summaries of the estimated annual usage of thiamethoxam as a seed

treatment and foliar/soil treatments are in **Tables 6 and 7**. When considering the SLUA data for this chemical, the majority of the mass applied per year is via seed treatment. Based on the estimated usage on corn (average percent crop treated in combination with acres planted), this represents an annual average of 24 million acres treated with thiamethoxam. For soybeans and again based on average percent crop treated, an estimated 13 million acres are treated with thiamethoxam (**Table 8**). Data are generally not available to inform usage of pesticides on non-agricultural applications (e.g., ornamentals, turf).

Table 6. Estimated annual usage of thiamethoxam applied via seed treatment (source: SLUAs) – Reporting Time 2005-2014

Crop	Lbs a.i. applied per year	PCT (annual average)	PCT (annual max)
Corn	300,000	25	45
Cotton	100,000	30	45
Potatoes	20,000	15	20
Sorghum	20,000	20	25
Soybeans	300,000	15	25
Sugar beets	2,000	5	10
Wheat	50,000	5	15
Total	792,000	NA	NA

NA = not applicable

PCT = percent crop treated

Table 7. Estimated annual usage of thiamethoxam applied via foliar or soil applications (source: SLUAs) – Reporting Time 2005-2014.

Crop	Lbs a.i. applied per year	PCT (annual average)	PCT (annual max)
Alfalfa	<500	<1	<2.5
Almonds	NA	NA	NA
Apples	2,000	5	20
Artichokes	<500	30	40
Beans, green	<500	<2.5	<2.5
Blueberries	<500	<2.5	<2.5
Broccoli	1,000	10	20
Brussels sprouts	<500	5	15
Cabbage	<500	5	20
Cantaloupes	NA	NA	NA
Caneberries	<500	15	25
Cantaloupes	1,000	5	25
Carrots	<500	5	10
Cauliflower	<500	5	20
Celery	1,000	20	50
Cherries	1,000	10	25
Chicory	<500	5	10
Cotton	60,000	10	15
Cucumbers	<500	5	10
Figs	NA	NA	NA
Dry Beans/Peas	<500	<1	<2.5
Grapefruit	2,000	25	65

Grapes	1,000	<2.5	5
Lemons	<500	5	10
Lettuce	2,000	10	35
Oranges	10,000	15	25
Peaches	1,000	5	15
Pears	1,000	20	35
Pecans	<500	<2.5	5
Peppers	1,000	15	35
Pistachios	<500	<1	<2.5
Plums/Prunes	<500	<2.5	<2.5
Pomegranates	NA	NA	NA
Potatoes	20,000	15	30
Pumpkins	<500	<2.5	10
Soybeans	10,000	<1	<2.5
Spinach	<500	5	10
Squash	<500	5	10
Strawberries	1,000	20	40
Tangerines	<500	5	10
Tobacco	<500	<2.5	5
Tomatoes	6000	10	20
Walnuts	NA	NA	NA
Watermelons	<500	5	10
Wheat	<500	<1	<2.5
Total	121,000-132,500	NA	NA

NA = not applicable

PCT = percent crop treated

Table 8. Estimated amount of acres treated with thiamethoxam via seed treatments (from 2016)

Crop	Millions of acres planted in 2016 (1)	Millions of acres treated (based on average PCT)	Millions of acres treated (based on max PCT)
Corn	94.1	24	42
Cotton	10	3.0	4.5
Potatoes	1.0	0.15	0.20
Sorghum	7.2	1.4	1.8
Soybeans	83.7	13	21
Sugar beets	1.1	0.06	0.11
Wheat	50.8	2.54	7.62

[1] http://www.usda.gov/nass/PUBS/TODAYRPT/acrg0616.pdf

2.1.3. Physical, Chemical, Fate and Transport Properties for Thiamethoxam

General physical, chemical and environmental fate properties of thiamethoxam, obtained from lab and field studies, are summarized in **Table 9**. Thiamethoxam is soluble (4100 mg/L) in water. The vapor pressure (4.95 x 10^{-11} mm Hg) and Henry's Law Constant (4.65 x 10^{-15} atm m³/mol) indicate that the compound is relatively non-volatile under field conditions. The compound does not dissociate within the range of pH 2 to 12. The n-octanol water partition coefficient (log K_{ow} = -0.13) for thiamethoxam indicates a low potential for bioaccumulation.

Table 9: Nature of the Chemical Stressor Thiamethoxam

Parameter	Value	MRID
Common name	Thiamethoxam	44703304
CAS number	153719-23-4	44703304
Chemical name	3-(2-Chloro-thiazolyl-5-ylmethyl)-5-methyl-	44702204
(IUPAC)	[1,3,5] oxadiazinan - 4-ylidene - N-nitroamine	44703304
Chemical Class	Neonicotinoid	44702204
Chemical Category	Insecticide	44703304
Empirical formula	$C_8H_{10}CIN_5O_3S$	44703304
Structure	H ₃ C N N N	44703304
Molecular mass (g/mol)	291.7	44703304
Water Solubility (25°C)	4100 mg/L	44703305
Vacci Soldshirty (25°C)	4.95 x 10 ⁻¹¹ mm Hg	44703305
Henry's Law Constant	4.63 x 10 ⁻¹⁵ atm m ³ /mol	Calculated ¹
Octanol/water partition	4.63 X 10 - aun m-/moi	Calculateu
coefficient (Log K _{ow})	-0.13 at 25°C	44703305
	572 and 643 days at pH 7 (stable)	44703416
Hydrolysis (t _{1/2})	4.2 and 8.4 days at pH 9	44703417
Direct Aqueous Photolysis	3.36	44715024
(t _{1/2} ; d)	3.90	44715025
Soil Photolysis	80	44715027
(t _{1/2} ; d)	97	44715028
	294	44703419
Aerobic Soil Metabolism	353	44703501
(t _{1/2} ; d)	101	44703418
	60.1	49589503
	174	49589504
	272	49589505
	188	49589506
	268	49589506
	464	49589506
	110	49589506
	136	49589506
	73.6	49589507
	143	49589507
	34.3	49589507
	81.3	49829901
Anaerobic Soil Metabolism	76.2	49829902
(t _{1/2} ; d)	77.7	49829902
	45.6	49829902
	118	49829902
	16.3	44715032
Aerobic Aquatic Metabolism	16.2	44715032
(t _{1/2} ; d)	35.1	49589509

Parameter	Value	MRID
Anaerobic Aquatic	28.6	44715029
Metabolism	25.3	44715030
(t _{1/2} ; d)	20.7	49589508
	77.2 for Sandy Clay Loam	
Soil Partition Coefficient	53.1 for Loam	44703502
(K _{oc} ; L/kg-oc)	176.7 for Sandy Loam	44703503
	43.0 for Sand	45640401
	38.3 for Loam	45084901
	33.1 for Silty Clay Loam	
	72-111 (seed treatment)	44703505
Terrestrial Field Dissipation	13 (broadcast application)	44727506
(t _{1/2} ; d)	70.7 (broadcast application)	44948902
	100.4 (furrow application)	45086202
	1.05 to 78.8 (turf)	44948903
	11 C to 17 2 (modd:tom)	47558101
Aquatic Field Dissipation	11.6 to 17.2 (paddy water)	47558102
(t _{1/2} ; d)	13.6 to 26.7 (paddy soil)	47558103

 $^{^{1}}$ = Henry's Law (atm-m 3 /mole) = (VAPR/760)/(SOL/MWT), where VAPR is vapor pressure in torr, MWT is molecular weight in g/mol, and SOL is the solubility in water in mg/L.

Degradation

In terrestrial environments, thiamethoxam is expected to be persistent, with half-lives on the order of months to years. Thiamethoxam persists from months to years in various aerobic soils with (14) half-lives ranging from 34.3 to 464 days (90^{th} percentile half-life = 236 days; half-life > 100 days in 11 of 14 studies) from (8) aerobic soil metabolism studies. Thiamethoxam persists for months with (5) anaerobic soil half-lives ranging from 45.6 to 118 days (90^{th} percentile half-life = 97 days) from two anaerobic soil metabolism studies. Photodegradation in soil is not expected to be a substantial route of dissipation, as half-lives range from 80 to 97 days in irradiated soil.

Thiamethoxam is less persistent in aquatic environments, with half-lives on the order of weeks. In aerobic aquatic metabolism studies, thiamethoxam degraded with half-lives ranging from 16.2 to 35.1 days in water sediment systems. Thiamethoxam showed similar persistence in anaerobic aquatic environments with half-lives ranging 20.7 to 28.6 days. In clear, alkaline waters, thiamethoxam is expected to be less persistent, as photodegradation in water (3.4-3.9 d) and alkaline-catalyzed hydrolysis (4.2-8.4 d) half-lives are on the order of days.

Major degradates are compounds that form at greater than 10% of the applied in at least one fate study. Major and minor (<10%) degradates including unextracted residues that have been identified in the thiamethoxam laboratory and field studies are listed in **Table 10** and their names, structures and percent formation are provided in **Appendix A**.

Soil Sorption and Mobility

Batch equilibrium studies indicate that thiamethoxam is mobile to moderately mobile in soils according to the FAO mobility classification (FAO, 2014). The adsorption, K_{oc} ranged from 33.1-176.7 L kg_{oc} . The study results indicate correlation between thiamethoxam adsorption to soil and percent organic carbon. No correlation is found between thiamethoxam adsorption and percent clay. The desorption K_{oc} values

were higher than the adsorption K_{oc} values, indicating that once adsorbed to soil, thiamethoxam would be less likely to be mobile in soil. Aged leaching studies also suggest that thiamethoxam becomes less mobile after aging. This data supports unextracted residues (**Table 10**) will most likely bind to soil and sediment. Given these lines of evidence in addition to the fact that exhaustive extraction techniques were utilized to extract thiamethoxam, unextracted residues were not included when calculating half-lives to assess aquatic exposure in this assessment.

Field Dissipation

Several field dissipation studies were conducted in the United States and Canada. Field dissipation half-lives for thiamethoxam following broadcast applications ranged from 13-70.7 days. A field dissipation half-life of 100 days was determined for an in-furrow application where an application rate that was 4.2 times greater than the broadcast rate was used. In studies conducted in 1997 in California, Florida, and Michigan, quantifiable thiamethoxam residues were detected at a maximum depth of 6-12 inches following broadcast applications. In a study conducted in 1998 in California, quantifiable thiamethoxam residues were detected at a 12-18 inches in turf plots and 18-24 inches in bare plots. In studies conducted in 1998 in California and New Jersey, quantifiable residues were detected at 6-12 inches in turf plots and 12-18 inches in bare plots. In a study that was conducted at four sites in Canada with thiamethoxam formulated as Helix seed treatment, thiamethoxam had half-lives that ranged from 72 to 111 days. A major transformation product in the field was clothianidin (CGA-322704) forming at 13.2%.

Two aquatic field dissipation studies of thiamethoxam under field conditions were conducted in Arkansas and Louisiana. These studies investigated the dissipation of thiamethoxam in a paddy water column (aquatic phase) and paddy soil when thiamethoxam was applied as a seed treatment. In Arkansas, thiamethoxam dissipated in both phases with a calculated dissipation half-life of 11.6 days in paddy water and 26.7 days in paddy soil. No major degradates were detected in the paddy soil or water column. In Louisiana, thiamethoxam dissipated in both phases a calculated dissipation half-life of 17.2 days in paddy water and 13.6 days in paddy soil. Major degradates CGA-355190 (10%) and CGA-353042 (10.2%) were observed in the water column.

Field dissipation half-lives are similar to or within an order of magnitude of degradation half-lives conducted in the laboratory.

Table 10. Degradates [Major (M) and Minor (m)] at Maximum Percent Formation¹ Identified in Laboratory and Field Studies

Degradate	Hydrolysis	Photolysis (aqueous)	Photolysis (soil)	Aerobic Soil	Anaerobic Soil	Aerobic Aquatic	Anaerobic Aquatic	TFD	AFD
CGA-265307				5.1	0.3				
CGA-282149			3.17	6.8					
CGA-309335	9.10			0.3					
CGA-322704			2.44	36.8	17.3		< 3.8	13.2	8.8
CGA-353042		60.7							10.2
CGA-353968			1.13	3.8		9.8	< 3.8		
CGA-355190	59.5		2.22	23.7	21.5	78.9	31.3	30	10.0
NOA-404617	35.2				7.6	36.0	7.7		
NOA-407475					14.2	52.0	69.1		9.1
NOA-459602					4.0				
SYN501406					2.6				
UER				21.4	14.2	59.1	51.2		
CO ₂				44.2	41.5	33.3	2.6		

¹Maximum percent formation from all available fate studies. Percent formation varies by individual study. **CGA-322704** is the active ingredient clothianidin.

TFD = Terrestrial Field Dissipation; AFD = Aquatic Field Dissipation; UER = Unextracted Residues

2.2. Aquatic Exposure Modeling

In this assessment, aquatic exposure modeling is not conducted for each individual registered crops/use site. Rather, the crops/uses modeled were selected to represent bracket exposures, with selected uses based on several lines of evidence, including: 1) agricultural crops, which based on previous risk assessments, presented a potential risk to honey bees (*i.e.*, citrus, cotton, cucurbits; USEPA 2017); 2) agricultural crops which, based on usage information, represent a majority use for thiamethoxam (*i.e.*, seed treatments); 3) uses intended to bracket a low and high-end range of EECs; and, 4) represent non-agricultural registered uses which account for some of the highest application rates (*i.e.*, turf, ornamentals, Christmas tree plantations).

Measures of exposure to aquatic organisms are pesticide concentrations in surface water. EECs are derived using the Pesticide in Water Calculator (PWC v 1.52), which couples the Pesticide Root Zone Model (PRZM v5.02, May 12, 2006a) and the Variable Volume Water Model (VVWM v.1.02.1) based on thiamethoxam use on crops, typically at maximum label use rates. The EECs used in risk assessment are simulated 1-in-10 year return frequency daily averages (acute assessments) and mean concentrations over a specified duration (21-d for invertebrates and 60-d for fish; chronic assessments) generated at the modeled site.

For aquatic exposure modeling, pesticide application information (scenarios, application rates and dates, etc.) were developed with consultation with the Biological and Economic Analysis Division (BEAD). For seed treatments, it is conservatively assumed that 100% of the chemical on the treated seed is available for environmental fate processes beyond its interaction with the plant. Planting (application) depths were consistent with those specified in the imidacloprid preliminary ecological risk assessment (USEPA, 2016b) and applications were modeled to occur 10 days prior to emergence, simulating planting. Depending on the crop, as well as regional agricultural practices, planting depth may be less than or greater than what is typically employed. Incorporation depth has

a significant impact on aquatic EECs, with deeper seeds resulting in lower EECs. Typical seeding depths were selected for use in PWC simulations for seed treatment uses. In PWC, for extraction of the chemicals from the soil into runoff, runoff flow is assumed to be constrained to a subsurface depth of 2 cm. As a result, if the seeding depth is greater than 2 cm (*i.e.* corn and wheat), the chemical is not extracted/available for runoff (*i.e.*, there is no dissolved pesticide in the runoff). The aquatic EECs for seed treatment generated in this assessment may under- or over-estimate concentrations typically seen in waterbodies receiving runoff from fields with treated seeds based on the actual planting depth of certain seeds.

PFAM was used to derive EECs for thiamethoxam use on rice seed and cranberry. The PFAM model simulates application of the pesticide to a wet or dry field and degradation in soil and/or water. If the pesticide is applied to dry soil, water may then be introduced into the field and movement of the pesticide may occur from soil into the water. After flooding, water may be held in a holding system, recirculated to other areas of the production facility, or released to adjacent waterbodies (canals, rivers, streams, lakes, or bays) external to the rice or cranberry fields. The cranberry bog water estimates are post-application residues in untreated flood water introduced into the treated cranberry field.

Release water EECs were calculated based on 30-years of simulated results based on flooding events (e.g., winter flooding and flooding during harvest for cranberry scenario). Also, the PWC tool was utilized for dry harvest cranberry exposure using the OR berry scenario. The PWC and PFAM input parameters are shown in **Table 11** and **Table 12**, respectively with the resulting EECs in **Table 13**. Representative PWC and PFAM outputs are presented in **Appendix C**.

Table 11. Chemical-Specific PWC Model Input Parameters for Thiamethoxam

Input Parameter:	Value:	Comment:	Source:
Scenario(s):	All Registered Crops	pesticide application information (scenarios, application rates and dates, etc.) were developed with consultation with BEAD.	Crop Scenarios See TMX batch file TMX batch file
Maximum Single Application Rate: lbs a.i./A (kg a.i./ha)	varies (see batch file)	registered rates	registered labels
Applications per Year	varies from 1 to 3	label directions. Some labels specify rates per season. If crops are rotated with those on which thiamethoxam is used, yearly rates may be higher.	registered labels
Application Interval (days)	varies from 5, 7, 10 days depending on crop (see batch file)	intervals were selected to reflect labeled application patterns.	registered labels

Input Parameter:	Value:	Comment:	Source:
Date of Initial Application (scenario/day/month)	See batch file	Application dates for foliar and soil treatments were selected based on the wettest month for the meteorological file specified in scenario during the potential use period. The 15 th of the month was randomly selected as the first application date. Application dates for seed treatments reflect planting 10 days before the emergence date specified in the scenario.	Crop Scenarios
Application Method	Aerial Ground Seed Treatment	label directions	registered labels
Seed Treatment Application Depth (cm)	Cotton = 1.27 Corn = 3.81 Soybean = 1.91 Sugarbeet = 1.27 Wheat = 2.54	Thiamethoxam seeding (application) depths were consistent with the imidacloprid preliminary ecological risk assessment.	USEPA, 2016b
Spray Drift Fraction	0.125 (aerial) 0.062 (ground) 0 (seed treatment)	label directions	Spray drift guidance (USEPA, 2013b)
Application Efficiency	0.95 (aerial) 0.99 (ground) 1.0 (seed treatment)	Generally aerial application scenarios generate higher drift exposure as compared to ground and chemigation scenarios	Input parameter guidance (USEPA, 2009)
Molecular Mass (g/mol)	291.7	product chemistry data	MRID 44703304
Vapor Pressure at 25°C (torr)	4.95 x 10 ⁻¹¹	product chemistry data	MRID 44703305
Solubility in Water at 25°C (mg/L)	4100	product chemistry data	MRID 44703305
Organic Carbon Partition Coefficient (K _{oc}) (L/kg _{oc})	70.23	represents the average K _{oc}	MRID 44703502
Aerobic Soil Metabolism Half-life (days) 20°C	236	represents the 90 th %-tile confidence bound on the mean half-life of 14 values.	MRID 44703418 MRID 44703419 MRID 44703501 MRID 49589503 MRID 49589504 MRID 49589505 MRID 49589506 MRID 49589507
Aerobic Aquatic Metabolism Half-life (days) 20°C	34.4	represents the 90 th %-tile confidence bound on the mean half-life of 3 values	MRID 44715032 MRID 49589509

Input Parameter:	Value:	Comment:	Source:
Anaerobic Aquatic Metabolism Half-life (days) 20°C	29.19	represents the 90 th %-tile confidence bound on the mean half-life of 3 values	MRID 44715029 MRID 44715030 MRID 49589508
Hydrolysis Half-lives (days)	0 (pH 7)	Considered stable ^a	MRID 44703417
Aqueous Photolysis Half-life (days) at 40° Latitude	4.46	represents the 90 th %-tile confidence bound on the mean half-life of 2 values	MRID 44715032

^a estimated half-lives of (572 and 643 days) are beyond the duration of 30-d study, thus considered stable.

Table 12. Chemical-Specific PFAM Model Input Parameters for Thiamethoxam

Input Parameter:	Value:	Comment:	Source:
Crop Cranberry	Scenario MA Cranberry Winter Flood OR Cranberry No Flood OR Cranberry Winter Flood WI Cranberry Winter Flood	Interim standard scenarios for cranberry	Crop Scenarios
Rice (seed)	MS Winter CA WInter	Rice scenarios selected based upon dry seeded (pre-flood timing) application	
Maximum Single Application Rate: Ibs a.i./A (kg a.i./ha)	Cranberry 0.063 (0.071) 0.188 (0.211) Rice (seed) MS 0.048 (0.054) CA 0.062 (0.070)	registered rates	registered labels
Applications per Year	1 (soil) to 2 (foliar) (cranberry) 1 (rice seed)	label directions	registered labels
Application Interval (days)	Not applicable (soil) 7 (foliar)	intervals were selected to reflect labeled application patterns.	registered labels
Date of Initial Application (scenario/day/mo nth)	6-15, 6-22 (cranberry) Rice (seed) MS 4-24 CA 5-13	Application dates for foliar and soil treatments were selected based on the wettest month for the meteorological file specified in scenario during the potential use period. The 15 th of the month was randomly selected as the first application date. Application dates for seed treatments reflect planting 10 days before the emergence date specified in the scenario.	Crop Scenarios
Application Method	Ground	label directions	registered labels

Input Parameter:	Value:	Comment:	Source:		
Drift Factor	No drift component for ERA	See guidance document	PFAM Model Input Guidance, (USEPA, 2016) ¹⁰		
Application Efficiency	Not applicable	See guidance document	PFAM Model Input Guidance, (USEPA, 2016) ³		
PFAM turn over/day	Not applicable for cranberry				
Heat of Henry (J/mol)	45,727	5500 (from HenryWin for thiamethoxam) x 8.314 (constant)	HenryWin v3.20		
Molecular Mass (g/mol)	291.7	product chemistry data	MRID 44703304		
Vapor Pressure at 25°C (torr)	4.95 x 10 ⁻¹¹	product chemistry data	MRID 44703305		
Solubility in Water at 25°C (mg/L)	4100	product chemistry data	MRID 44703305		
Organic Carbon Partition Coefficient (K _{oc}) (L/kg _{oc})	70.23	represents the average K _{oc}	MRID 44703502		
Aerobic Soil Metabolism Half- life (days) 20°C	236	represents the 90 th %-tile confidence bound on the mean half-life of 14 values.	MRID 44703418 MRID 44703419 MRID 44703501 MRID 49589503 MRID 49589504 MRID 49589506 MRID 49589506 MRID 49589507		
Aerobic Aquatic Metabolism Half- life (days) 20°C	34.4	represents the 90 th %-tile confidence bound on the mean half-life of 3 values	MRID 44715032 MRID 49589509		
Anaerobic Aquatic Metabolism Half- life (days) 20°C	29.19	represents the 90 th %-tile confidence bound on the mean half-life of 3 values	MRID 44715029 MRID 44715030 MRID 49589508		
Hydrolysis Half- lives (days)	0 (pH 7)	Considered stable ^a	MRID 44703417		
Aqueous Photolysis Half-life (days) at 40° Latitude	4.46	represents the 90 th %-tile confidence bound on the mean half-life of 2 values	MRID 44715032		
^a estimated half-live	es of (572 and 643 days) are beyond	the duration of 30-d study, thus co	nsidered stable.		

_

 $^{^{10}\} https://www.epa.gov/sites/production/files/2016-10/documents/pfam-input-parameter-guidance.pdf$

Table 13: Thiamethoxam Aquatic Modeling Inputs and Aquatic Exposure Concentrations (EECs)

Use	PWC Scenarios ¹	Application Rate (lbs a.i/A)	Application	Application		1 in 10) Year	
			Application Date(s) ²	Application Method ³	Peak (μg/L)	1-day (μg/L)	21-day (μg/L)	60-day (μg/L)
		Fo	iar Application					
Cotton	MS cotton	0.063, 0.063	6/15, 6/20	Aerial	3.06	3.01	2.49	1.56
				Ground	2.90	2.85	2.29	1.43
			6/15, 6/20	Aerial	1.06	1.05	0.82	0.53
	CA cotton			Ground	0.66	0.66	0.52	0.33
	FL potato		2/15, 2/22	Aerial	2.66	2.64	2.30	1.72
Potato		0.05, 0.05		Ground	2.44	2.43	2.11	1.57
. 53435	ID potato		6/15, 6/22	Aerial	0.73	0.73	0.64	0.47
				Ground	0.41	0.41	0.36	0.27
Cucurbits/fruiting vegetables/low growing berries/leafy vegetable	FL cucumber	0.086, 0.086	10/15, 10/22	Aerial	5.47	5.38	4.02	2.63
				Ground	5.12	5.03	3.76	2.59
	CA lettuce		2/15, 2/22	Aerial	2.97	2.95	2.58	2.04
				Ground	2.49	2.48	2.19	1.75
Grapes	Not modeled; bounded by potato and cucurbits/fruiting vegs/low growing/leafy veggies							
Cranberry	OR Berry (terrestrial)	0.063, 0.063	6/15, 6/22	Ground	0.53	0.52	0.45	0.33
	PFAM (highest EECs from 3 scenarios)			Ground	11.4	11.4	11.4	10.9
Tree fruit and nuts	OrchardBSS	0.086, 0.086, 0.086	5/15, 5/25, 6/4	Aerial	4.86	4.80	4.14	2.88
	0.080,	0.080, 0.080, 0.080		Ground	4.50	4.45	3.85	2.60
	CA almonds 0.063, 0.0	0.002.0.002	6/15, 6/22	Aerial	0.90	0.89	0.73	0.53
		0.063, 0.063		Ground	0.50	0.49	0.42	0.31
Ornamental	TN nursery	0.266	7/15	Ground	2.82	2.77	2.16	1.33
	CA nursery		3/15	Ground	1.11	1.10	0.95	0.72
Turf	FL turf	0.266	6/15	Ground	1.47	1.44	1.14	0.75

		Application Rate (lbs a.i/A)	Application Date(s) ²	Application Method ³	1 in 10 Year			
Use	PWC Scenarios ¹				Peak (μg/L)	1-day (μg/L)	21-day (μg/L)	60-day (μg/L)
	CA turf		1/15	Ground	3.82	3.80	3.39	2.72
Forestry	OR Xmas tree	0.255	12/15	Aerial	3.08	3.06	2.78	2.32
	NC apples	0.266	5/15	Aerial	5.87	5.82	5.02	3.76
		Sc	oil Application				,	
Citrus	FL citrus	0.175	5/15	Ground	3.27	3.22	2.70	1.74
Potato	Not r	nodeled; bounded by	radish and grapes					
Cucurbits/fruiting vegetables/low	FL cucumber	0.470	10/15	Ground	4.01	3.94	2.95	2.18
growing berries/leafy CA lettuce vegetable	CA lettuce	0.170	2/15	Ground	3.82	3.79	3.34	2.60
B (*)	FL Carrot	0.10	01/15	Ground	2.30	2.28	1.91	1.42
Radish	CA Onion		02/15	Ground	0.35	0.35	0.31	0.25
Grape	NY grapes	0.27	6/15	Ground	2.10	2.08	1.71	1.20
	CA wine grapes		5/15	Ground	0.95	0.94	0.82	0.63
	OR Berry (terrestrial)	0.188		Ground	0.74	0.74	0.65	0.50
Cranberry	PFAM (highest EECs from 3 scenarios)		6/15	Ground	16.8	16.8	16.7	16.0
Tree fruit & nuts	Not a use							
Ornamental	TN nursery	0.266	7/15	Ground	2.77	2.72	2.17	1.32
	CA nursery		3/15	Ground	1.06	1.05	0.91	0.69
T¢	FL turf	0.266	6/15	Ground	1.19	1.17	0.91	0.59
Turf	CA turf		1/15	Ground	3.09	3.08	2.75	2.19
Forestry	OR Xmas tree	0.266	12/15	Ground	1.99	1.98	1.77	1.44
	CA forestry		5/15	Ground	3.69	3.65	3.13	2.18
		Se	ed Treatment ⁴					
Cotton	MS cotton	0.044	5/15	Incorporated	0.51	0.51	0.42	0.26
	CA cotton	0.071 ⁵	4/21	1.27 cm	0.09	0.08	0.07	0.05

Use	PWC Scenarios ¹	Application Rate (lbs a.i/A)	Application Date(s) ²	Application Method ³	1 in 10 Year			
					Peak (μg/L)	1-day (μg/L)	21-day (μg/L)	60-day (μg/L)
Corn	MS corn	0.097	5/15	Incorporated	0.00	0.00	0.00	0.00
	CA corn	0.113 ⁶	3/22	3.81 cm	0.00	0.00	0.00	0.00
Soybean	MS soybean	0.053	5/7	Incorporated	0.03	0.03	0.02	0.02
	CA corn	0.083 ⁷	3/22	1.91 cm	0.01	0.01	0.01	0.01
Sugarbeet	MN sugar beet	0.064	5/6	Incorporated 1.27 cm	0.28	0.27	0.25	0.19
	CA sugar beet	0.1678	1/22		0.54	0.54	0.50	0.41
Wheat	TX wheat	0.047	10/6	Incorporated 2.54 cm	0.00	0.00	0.00	0.00
	CA wheat	0.081 ⁹	11/15		0.00	0.00	0.00	0.00
Rice (PFAM)	MS Rice	0.048	4/24	Incorporation	4.14	4.13	3.81	2.78
	CA Rice	0.06210	5/13	not applicable	68.9	66.4	35.5	16.2

- 1. Additional scenarios are available for other parts of the country for this use. Scenarios are selected to represent a high-end runoff scenario (first scenario) and a low-end runoff, drift driven scenario (second scenario). Scenarios are meant to represent the east coast and west coast, with EECs for scenarios for midwestern states lying somewhere in between the two.
- 2. Application dates (month/day) for foliar and soil treatments selected based on the wettest month for the meteorological file specified in scenario during the potential use period. The 15th of the month was randomly selected as the first application date. Application dates for seed treatments reflect planting 10 days before the emergence date specified in the scenario. EFED will be modeling one crop cycle per year for all crops.
- 3. Spray drift fractions 0.125 (aerial), 0.062 (ground), 0 (incorporated).
- 4. Application assumed to occur 10 days prior to emergence date in PWC scenario.
- 5. 8.3 x 10^{-7} lb a.i/seed x 52,500 seed/A (from LA) and 85,000 seed/A in CA.
- 6. 2.8 x 10⁻⁶ lb a.i/seed x 59,739 seed/A. MI (actually MO): 26,400-34,500 seeds/acre; CA (max across states): 40,250 seeds/acre
- 7. 3.3 x 10⁻⁷ lb a.i/seed (Cruiser 5FS). MI (MO): 150,000-160,000 seeds/acre; CA (max across states): 250,000 seed/acre.
- 8. 1.6 x 10⁻⁶ lb a.i/seed x 40,000 seed/acre (MN) and 104,544 seed/A (CA)
- 9. 5.2 x 10^{-4} lb a.i/lb seed x 90 lb seed/A (TX) and 156 lb seed/A (CA)
- 10. 5.2 x 10⁻⁴ lb a.i/lb seed x 92 lb seed/acre (drill seeding; MS) and 120 lb seed/acre (water seeding; CA

2.3. Aquatic Exposure Monitoring Data

Monitoring data for thiamethoxam (Table 14) are available from the United States Geological Survey (USGS) National Water-Quality Assessment (NAWQA) Program Data Warehouse¹¹, searched on June 22, 2017. Access to the NAWQA monitoring data is now through the Water Quality Portal (WQP) website, which integrates public available water quality data from the USGS National Water Information System (NWIS), the EPA STOrage and RETrieval (STORET) Data Warehouse, and the USDA ARS Sustaining the Earth's Watersheds Agricultural Research Database System (STEWARDS). Thiamethoxam was detected in 216 of 2498 (8.7%) of surface water samples across 24 states; the reported maximum concentration (4.37 μg/L) was detected in California. This particular sample was a routine surface water sample was collected on September 28, 2016 by the USGS California Water Science Center and analyzed by LC/MS/MS. The detected concentrations of available monitoring data are within the same order of magnitude of the modeled surface water exposure estimates. Thiamethoxam was detected in 82 of 1935 (4.2%) ground water samples all of which were detections from Minnesota; the reported maximum concentration was 2.11µg/L. The detected concentration of monitoring data is an order of magnitude lower than the modeled ground water exposure estimates. However, the study design of NAWQA is not targeted to account for all thiamethoxam use areas; timing of application and other factors which may more accurately represent spatially and temporally dependent variables influencing runoff vulnerability.

Monitoring data for surface water and ground water from the California Department of Pesticide Regulation (CDPR) 12 was searched on June 22, 2017. Thiamethoxam was detected in 26 of 507 (5.1%) surface water samples across California; the reported maximum concentration was 4.37µg/L. The detected concentration of monitoring data is within the same order of magnitude compared to the modeled surface water exposure estimates. For ground water, thiamethoxam was detected in 27 wells in 2015 and 64 wells in 2016, but all samples were below the reporting limit of 0.05 µg/L.

Table 14. Monitoring Data Summary for Thiamethoxam in Groundwater and Surface Water

Monitoring Program	Water Type	Detects	Samples	Detection Frequency (%)	LOD (μg/L)	Maximum Concentration (μg/L)
NAWQAª	Surface Water	216	2498	8.7	0.02	4.37
NAVVQA	Ground Water	82	1935	4.2	0.02	2.11
	Surface Water	26	507	5.1	0.02	4.37
CDPR ^a	GW 2015	27	27	100	0.05	< 0.05
	GW 2016	64	64	100	0.05	< 0.05

^aData downloaded from the Water Quality Portal on June 22, 2017. Data sources are combined so there is the potential for duplicative data, which could skew interpretation.

The following open literature information was available about neonicotinoids (thiamethoxam) presence in surface waters. Detected thiamethoxam concentrations vary and are typically within an order of magnitude of the estimated environmental concentrations modeled in this assessment.

¹² http://www.cdpr.ca.gov/docs/emon/surfwtr/surfdata.htm

Hladik *et al* (2014) investigated an area of intense corn and soybean production in the Midwestern United States to evaluate neonicotinoid presence in surface water. Study authors reported high agricultural use of neonicotinoids via both seed treatments and other forms of application occur in this region. Water samples were collected from nine stream sites (eight in lowa and one in Nebraska, basin areas spanning 521 to 836,000 km²) during the 2013 growing season (3/9/2013 to 11/1/2013). Reported clothianidin concentrations ranged from non-detect to 257 ng/L, with a median value of 8.2 ng/L (n=79, number of non-detects = 20). Thiamethoxam concentrations ranged from non-detect to 185 ng/L, with a median value < 2 ng/L (n=79, number of non-detects = 42). Dinotefuran was not detected in any of the 79 samples. The level of detection was 2 ng/L. Clothianidin and thiamethoxam were detected at all nine sites sampled. Study authors reported temporal patterns in concentrations associated with rainfall events during crop planting, suggesting seed treatments as the likely source of the neonicotinoids.

According to Raina-Fulton, R. (2016), neonicotinoids have been detected in 63% of the 48 streams sampled across the United States with clothianidin having a detection frequency of 24% (maximum 66 ng/L), thiamethoxam having a detection frequency of 21% (maximum 190 ng/L), and dinotefuran having a detection frequency of 13% (maximum 130 ng/L)¹³. Clothianidin and thiamethoxam concentrations in surface water were positively correlated with land use in cultivated crops and imidacloprid was positively correlated with urban area within the water basin. Precipitation was identified as an important driver for neonicotinoid transport in the environment following periods of use¹⁵. In maize producing counties of southwestern Ontario in Canada, 100% of 76 samples collected had clothianidin and 98.7% had thiamethoxam with mean concentrations of clothianidin and thiamethoxam at 2,280 and 1,130 ng/L, respectively (maximum 43,600 and 16,500 ng/L, respectively)¹⁴. The highest concentrations in field occurred in a puddle with total concentration of neonicotinoid insecticides (clothianidin and thiamethoxam) of 44,380 ng/L as compared to outside the treated seed field in puddle, ditch and drain concentrations at 17,830, 12,250, and 6,210 ng/L¹⁶. Total concentration of neonicotinoids were 4.6 and 5.9 times higher in week 1-3 and 4-5 after planting with treated corn seed as compared to 1-2 weeks before planting and returned to similar concentrations of neonicotinoids to before planting by week 6- 7^{16} . In water from Canadian prairie wetlands of central Saskatchewan (located within a region of high neonicotinoid seed treatment use for wheat and canola) the highest detection frequency (62%) and highest concentrations of neonicotinoids (maximum 3,110 ng/L, mean 76.8 ng/L) occurred in summer with clothianidin greater than thiamethoxam¹⁵. Other areas with soil-applied neonicotinoids (thiamethoxam, clothianidin and imidacloprid) for potato production have detected thiamethoxam and clothianidin at 210 to 3,340 ng/L (average 620 ng/L) and 260-3,340 ng/L (average 790 ng/L) in ground water with the highest frequency of detection for thiamethoxam (during 2008-2012) suggesting high leaching potential 16. In addition, cycling of contaminated ground water due to use of high capacity irrigation wells occurred.

-

¹³ Hladik ML, Koplin DW. First national-scale reconnaissance of neonicotinoid insecticides in streams across the USA. Environ. Chem. 2016; 13: 12-20

¹⁴ Schaafsma A, Limay-Rios V, Baute T, Smith J, Xue Y, et al. Neonicotinoid insecticide residues in surface water and soil associated with commercial maize (corn) fields in southwestern Ontario. PLoS One. 2015; 10: e0118139.

¹⁵ Main AR, Michel NL, Headley JV, Peru KM, Morrissey CA, et al. Ecological and Landscape Drivers of Neonicotinoid Insecticide Detections and Concentrations in Canada's Prairie Wetlands. Environ Sci Technol. 2015; 49: 8367-8376.

¹⁶ Huseth AS, Groves RL. Environmental fate of soil applied neonicotinoid insecticides in an irrigated potato agroecosystem. PLoS One. 2014; 9: e97081.

Struger et al (2017) conducted a wide scale investigation of neonicotinoid insecticides used across the range of agricultural activities from fifteen surface water sites in southern Ontario. The fifteen sites consisted of nine streams near agricultural areas (drainage area <100 km²), and six larger streams/rivers (drainage area >100 km²). The stream sites reflected a range of agricultural activities including row crops, fruits and vegetables, orchards and grapes, greenhouses, ornamental nurseries, and turf. The sites also included an urban stream (Indian Creek) and a reference stream (Spring Creek) located adjacent to a national park removed from agricultural activities. All neonicotinoid insecticide concentrations in samples from Spring Creek were below the method detection limits (1.76 ng/L for clothianidin and 1.39 ng/L for thiamethoxam). Seventeen precipitation samples in total were collected between May and October 2013 at Bear Creek in southern Ontario. Bi-monthly integrated precipitation samples were collected using a MIC-B-wet-only automated precipitation sampler. Concentrations for clothianidin and thiamethoxam are presented in Table 15. Clothianidin concentrations ranged from non-detect to 399 ng/L in surface water, while thiamethoxam ranged from non-detect to 1340 ng/L. Neonicotinoids were rarely detected in precipitation at Bear Creek in 2013; most detections were during the period of 14-31 May 2013. Concentrations in precipitation of thiamethoxam and clothianidin on May 14th, 2013 were 114 ng/L and 120 ng/L, respectively. The study authors speculated that the detections may have been the result of drift of dust generated during application on row crops, or planting of treated seeds during the spring planting period, as the Bear Creek site is in proximity to the Lebo Drain and Sturgeon Creek stations, both of which are characterized by greater than 60% row crop agriculture. Using statistical analysis, study authors investigated the correlation of individual compounds with land use and assessed the relationship between neonicotinoid occurrence and hydrologic parameters in calibrated water courses. Of the five neonicotinoids studied, clothianidin and thiamethoxam exhibited detection rates above 90% at over half the sites sampled over a three-year period (2012-2014). For some watersheds, study authors found correlations between the occurrence of neonicotinoids and precipitation and/or stream discharge. Some watersheds exhibited seasonal maxima in concentrations of neonicotinoids in spring and fall, particularly for those areas where row crop agriculture is predominant; these seasonal patterns were absent in some areas characterized by a broad range of agricultural activities.

Table 15. Summary statistics for neonicotinoids measured in southwestern Ontario surface waters¹

Site	N	N (non-detect)	Median (ng/L)	Mean (ng/L)	Stdev	Detection Frequency (%)	Maximum (ng/L)
		l	Clot	hianidin			
Twenty Mile							
Creek	36	0	22.1	31.6	27.6	100.0%	133
Two Mile Creek	42	28	<1.76	13.8	63.3	33.3%	399
Four Mile Creek	41	6	4.01	13.3	32.9	85.4%	177
Big Creek	14	8	<1.76	4.19	8.67	42.9%	32.7
West Holland							
River	13	1	6.7	7.78	5.44	92.3%	19.1
Indian Creek	35	27	<1.76	2.65	1.75	22.9%	9.07
Innisfil Creek	26	2	4.83	7.28	8.11	92.3%	42.8
Lebo Drain	27	0	31.4	41.8	27.3	100.0%	125
Nissouri Creek	12	0	11.6	22.8	27.6	100.0%	104
Nottawasaga							
River	26	5	7.28	11.1	11.2	80.8%	50.7

	Ţ	·	T	Υ	7	Υ	Ţj
Spring Creek	18	18	<1.76	-	-	0.0%	<1.76
Sturgeon Creek	39	8	3.81	5.17	5.05	79.5%	27.7
Sydenham River	42	0	18	28.7	32	100.0%	182
Thames River	30	0	11.7	17.5	16	100.0%	61.1
Prudhomme							
Creek	39	2	7.66	22.3	32.6	94.9%	132
			Thiam	ethoxam			
Twenty Mile							
Creek	36	0	50.4	172	266	100.0%	1340
Two Mile Creek	42	26	<1.39	5.79	6.75	38.1%	25.1
Four Mile Creek	41	15	4.01	17.8	30	63.4%	123
Big Creek	14	8	<1.39	4.69	11.2	42.9%	41.5
West Holland							
River	13	0	16.3	21.2	22.3	100.0%	79.4
Indian Creek	35	25	<1.39	7.11	31.5	28.6%	181
Innisfil Creek	26	0	9.06	20.1	32.9	100.0%	137
Lebo Drain	27	0	101	137	125	100.0%	546
Nissouri Creek	12	4	2.02	4.28	4.8	66.7%	17.7
Nottawasaga							
River	26	0	12.9	23.5	24.9	100.0%	84.4
Spring Creek	18	18	<1.39	-	_	0.0%	<1.39
Sturgeon Creek	39	1	8.42	12.5	10.8	97.4%	47.8
Sydenham River	42	1	10.6	58.6	142	97.6%	743
Thames River	30	0	11.1	24.9	31.2	100.0%	126
Prudhomme							
Creek	39	11	3.16	15.3	37	71.8%	143

^{1.} Mean, Median, and Standard Deviation (Stdev) were estimated using the Kaplan-Meier method for censored datasets (Helsel 2012).

In 2017, Miles et. al. conducted field surveys to determine neonicotinoid concentrations in soil and water samples from multiple sites in Tippecanoe Co., Indiana. Study authors tested for acetamiprid, clothianidin, imidacloprid, and thiamethoxam in soil and water. The four sampled locations had an associated stream or ditch that served as a location for our water samples. One site was selected because it contained wetland areas that would allow assessment of neonicotinoid concentrations in lentic water bodies. Sampling was performed at each site two weeks prior to planting and weekly from two through eight weeks post-planting. Only water sampling was conducted at two of the sites. Thiamethoxam was not detected any of the soil samples (n = 32). Thiamethoxam was detected in 98% of water samples (n = 48). The mean thiamethoxam concentration across all sites and sample periods was 302,000 ng/L, with a maximum concentration of 2,568,000 ng/L obtained from a water (stream) sample from the Martell Forest location. In general, concentrations tended to peak 5 to 7 weeks post planting. Clothianidin was detected in 81% of the soil samples (n = 32). The mean clothianidin concentration in soils across all sites and sampling periods was 24,200 ng/kg, with a maximum concentration of across all sites and sample periods of 176,000 ng/kg. Peak concentrations tended to occur 4 weeks post planting. Clothianidin was detected in 96% of water samples (n = 48). The mean clothianidin concentration across all sites and sample periods was 100 ng/L, with a maximum concentration of 670 ng/L.

Since 2003, the Washington State Departments of Agriculture and Ecology has been conducting a multi-year monitoring program to characterize pesticide concentrations in selected salmon-bearing streams during the typical pesticide application season (March - September) in Washington. In 2014 monitoring was conducted in seven Water Resource Inventory Areas (WRIAs), five agricultural and two urban basins, for a total of 15 sample sites. Sampling was conducted weekly at most monitoring locations for 27 consecutive weeks, beginning the second week in March and continuing through to the second week in September. Surface water samples were collected by hand-compositing grab samples from quarter-point transects across each stream. In situations where streamflow was vertically integrated, a one-liter transfer container was used to dip and pour water from the stream into sample containers. Additionally, several conventional water quality parameters were measured: pH, conductivity, continuous temperature data (collected at 30-minute intervals), dissolved oxygen, and streamflow. Laboratory surrogate recovery, laboratory blanks, laboratory control samples (LCS), and laboratory control sample duplicates (LCSD) were analyzed as the laboratory component of QA/QC. Field blanks, field replicates, matrix spikes (MS), and matrix spike duplicates (MSD) integrated field and laboratory components. Sixteen percent of the field samples analyzed in 2014 were QA samples. In 2014, the program began to monitor for clothianidin (lower practical quantitation limit of 50 ng/L). None of the samples collected in 2014 contained detectable levels of clothianidin. Thiamethoxam was detected at 7 sampling sites in 4 WRIAs at concentrations ranging from 6 to 53 ng/L (n=405, detects=41). Dinotefuran was detected at 3 sampling sites in 2 WRIAs at concentrations ranging from 9 to 4480 ng/L (n=405, detects=49).

From 2012-2013, Main et. al. evaluated the potential impact to ecologically significant wetlands in Canada's major Prairie crop growing region to seed treatments of neonicotinoids. Study authors modelled the spatial distribution of neonicotinoid use across central Saskatchewan in combination with temporal assessments of water and sediment concentrations in wetlands to measure four active ingredients (clothianidin, thiamethoxam, imidacloprid and acetamiprid). From 2009 to 2012, neonicotinoid use increased from 7.7 million hectares to nearly 11 million hectares (44% of Prairie cropland) and from 150,000 kg to 216,000 kg of active ingredients. The dominant seed treatments by mass and area were thiamethoxam followed by clothianidin. Areas of high neonicotinoid use were identified as high density canola or soybean production. Water sampled four times (spring, summer, fall 2012 and spring 2013) from 136 wetlands across four rural municipalities in Saskatchewan similarly revealed clothianidin and thiamethoxam in the majority of samples. A summary of the results is provided in Table 16. In spring 2012 prior to seeding, 36% of wetlands contained at least one neonicotinoid. Detections increased to 62% in summer 2012, declined to 16% in fall, and increased to 91% the following spring 2013 after ice-off. Peak concentrations were recorded during summer 2012 for both thiamethoxam (1490 ng/L, LOQ=1.8 ng/L) and clothianidin (3110 ng/L, LOQ=1.2 ng/L). Sediment samples collected during the same period rarely (6%) contained neonicotinoid concentrations (≤ 20 ng/L). Wetlands situated in barley, canola and oat fields consistently contained higher mean concentrations of neonicotinoids than in grasslands, but no individual crop singularly influenced overall detections or concentrations. Study authors concluded that frequently detected neonicotinoid concentrations in Prairie wetlands suggested high persistence and transport into wetlands.

In 2015 **Morrissey** *et. al.* conducted a review to synthesize the current state of knowledge on the reported concentrations of neonicotinoids in surface waters from 29 studies in 9 countries world-wide. Neonicotinoids were detected in most surface waters sampled, including puddled water, irrigation channels, streams, rivers, and wetlands in proximity to, or receiving runoff from, agricultural cropland. Strong evidence exists that water-borne neonicotinoid exposures are frequent, long-term and at levels

(geometric means = 130 ng/L (averages) and 630 ng/L (maxima)) which commonly exceed several existing water quality guidelines. Thiamethoxam was assessed in eleven studies, seven of which were conducted in the United States or Canada with dates ranging from 2005 to 2013. Reported detection limits ranged from 0.63 to 100 ng/L. Mean detected concentrations across the studies ranged from 2.65 to 7,700 ng/L, while maximum detected concentrations across the studies ranged from 1.1 to 225,000 ng/L. Reported detections ranging from 3-100% of the samples collected. In one study thiamethoxam was detected in ground water in Wisconsin at a maximum concentration of 8,930 ng/L and a mean concentration of 1,590 ng/L. A summary of the results is provided in **Table 17**. The highest concentrations in surface water resulted from sampling of playa wetlands in Texas.

Table 16. Neonicotinoid concentrations in Canadian prairie wetlands

Saaran	Cunn	Wetlands	Detection	Total Neon	ic. (ng/L)	Thiametho	xam (ng/L)	Clothianidin (ng/L)		
Season	Crop	(n)	(%)	Mean	Max	Mean	Max	Mean	Max	
	Barley	28	29	5.8	41.1	ND	ND	3.9	39.4	
	Canola	54	52	20.7	184	2.5	19.1	16.3	144	
	Oats	15	47	5.8	21.7	1.3	7	3.6	20	
Spring, 2012 (pre-seed)	Peas	0	NS	NS	NS	NS	NS	NS	NS	
(pre seed)	Wheat	24	25	8.3	52.7	4.3	32.4	3.1	20.2	
	Grassland	15	7	1.1	7.9	ND	ND	1.1	7.9	
	Overall	136	36	8.3	184		32.4 (10%)		144 (36%)	
	Barley	18	83	78.9	322	19.3	91.3	57.8	277	
	Canola	61	70	185	3110	40.3	1490	142	3110	
Summer, 2012 (growing)	Oats	3	100	131	235	121	234	9.4	27	
	Peas	8	50	9.6	28.4	ND	ND	9.6	28.4	
	Wheat	29	62	53.5	524	2.3	37.7	35	518	
	Grassland	15	13	2.7	5.8	ND	ND	0.8	4.1	
	Overall	134	62	76.8	3110		1490 (19%)		3110 (51%)	
	Barley	13	8	1.1	7	ND	ND	1.1	7	
	Canola	35	20	5.4	32.6	2.2	20	2	30.9	
5 U 2042	Oats	3	33	4.2	12	ND	ND	ND	ND	
Fall, 2012 (harvest)	Peas	5	40	5.3	16	3.6	14.6	ND	ND	
(Harvest)	Wheat	15	0	ND	ND	ND	ND	ND	ND	
	Grassland	9	22	13.5	101	11.9	100	ND	ND	
	Overall	80	16	4	101		100 (6%)		30.9 (5%)	
	Barley	16	94	74.9	212	19.8	107	53.2	157	
	Canola	51	98	53.1	178	12.6	93.5	38.5	173	
Spring, 2013	Oats	3	100	60.7	102	41.9	79.4	16.9	20.4	
(pre-seeding)	Peas	6	100	33.3	60.6	ND	ND	33.3	60.6	
	Wheat	9	89	41.4	85.3	18.2	58.2	21.4	30.7	
	Grassland	5	0	ND	ND	ND	ND	ND	ND	

	Overall	90	91	52.7	212		107 (23%)		173 (87%)
--	---------	----	----	------	-----	--	-----------	--	-----------

Table 17. Summary of reported surface and ground water concentrations of neonicotinoids

Chemical	Year	Location	Water body	Land use	Detection Limit (µg/L)	Mean concentration (μg/L)	Max Concentration (μg/L)	Detections	Source reference
Clothianidin	2012	Quebec, Canada	Rivers	Agricultural (Corn and soybean)	NA	NA	0.37	NA	Giroux 2014 pers comm
Clothianidin	2013	Sydney, Australia	Rivers	Agricultural (vegetable and horticultural crops)	0.017	0.06 ± 0.13	0.42	53%	Sanchez-Bayo and Hyne 2014
Clothianidin	2012- 13	Quebec, Canada	Ponded water on fields	Agricultural (corn)- during and post seeding	1.0	4.6	55.7	92–100%	Samson-Roberts et al (submitted)
Clothianidin	2012- 13	Saskatchewan, Canada	Prairie wetlands	Agricultural (canola, cereals, grasslands)	0.0012	0.004 – 0.077*	3.1	5-87%	Main et al. 2014
Clothianidin	2009- 10	Osaka, Japan	Estuaries and rivers	Urban, rice upstream	0.00062	0.0032	0.012	100%	Yamamoto et al. 2012
Clothianidin	2011- 12	Wisconsin	Leachate (irrigation water)	Agricultural (potato, row crops-irrigated)	0.02	0.056	0.225	NA	Huseth and Groves 2014
Clothianidin	2008- 2012	Wisconsin	Groundwater	Agricultural (potato, row crops)	NA	0.62	3.43	25%	State of Wisconsin Dept. of Agriculture Trade and Consumer Protection (in Huseth and Groves 2014)
Clothianidin	2013	Iowa, USA	Rivers	Agricultural	0.0062	0.008**	0.257	75%	Hladlik et al. 2014
Dinotefuran	2009- 10	Osaka, Japan	Estuaries and rivers	Urban, rice upstream	0.00047	0.019	0.22	100%	Yamamoto et al. 2012
Dinotefuran	2013	Iowa, USA	Rivers	Agricultural	0.0055	NA	0.0027	1%	Hladlik et al. 2014
Imidacloprid	2010- 11	California, USA	Rivers, creeks, drains	Agricultural	0.05	0.77	3.29	89%	Starner and Goh 2012
Imidacloprid	2008- 11	California, USA	Surface water	Urban	NA	0.05	0.67	51%	Ensminger et al 2013
Imidacloprid	2009- 10	Osaka, Japan	Estuaries and rivers	Urban, rice upstream	0.00088	0.0055	0.025	100%	Yamamoto et al. 2012

Chemical	Year	Location	Water body	Land use	Detection Limit (µg/L)	Mean concentration (μg/L)	Max Concentration (μg/L)	Detections	Source reference
Imidacloprid	2006- 07	California, USA	Stormwater ponds	Urban	0.3	NA	9.0	7.1–10%	DeLorenzo et al. 2012
lmidacloprid	2001- 02	Rio Grande do Sul, Brazil	Groundwater Wells	Tobacco	0.05	1.93 ± 1.69	6.22	28%	Bortoluzzi et al. 2007
Imidacloprid	2001- 02	Rio Grande do Sul, Brazil	Creeks, agricultural channels	Tobacco	0.05	1.17 ± 0.77	2.59	19%	Bortoluzzi et al. 2007
Imidacloprid	2011- 12	Georgia, USA	Streams	Forest, urban and agricultural	0.0049	NA	0.035	74%	Hladlik and Calhoun 2012
Imidacloprid	2005- 07	Georgia/N Carolina, USA	Stream	Forests	0.6	<1.0	NA	NA	Churchel et al. 2011
Imidacloprid	2002- 03	Mato Grosso, Brazil	Groundwater	Agricultural (cotton)	0.57	ND	ND	0%	Carbo et al. 2008
Imidacloprid	2003- 06	New Brunswick, Canada	Streams	Agricultural, urban, forested	0.002	0.004 and 0.067	0.42, 0.46 (outlet)	7% ≥MDL 0.002	Xing et al. 2013
Imidacloprid	2003- 04	New Brunswick and PEI, Canada	Runoff, Streams	Agricultural	NA	0.25 ± 0.07 to 15.88 ±0.99	NA	NA	Dunn 2004
Imidacloprid	2000- 01	New York, USA	Streams	Forest 80%, Urban 13%, Agricultural 3.1%	0.106	NA	0.13	40%	Phillips and Bode 2004
Imidacloprid	2003- 05	New Brunswick, Canada	Agricultural streams	Agricultural	0.2	NA	NA	3.6%	Murphy et al. 2006 Env Can report
Imidacloprid	2008	Northern Vietnam	Streams	Agricultural (rice paddies)	0.001	0.12 - 0.19	0.22	100%	Lamers et al. 2011
Imidacloprid	2008	Northern Vietnam	Groundwater wells	Agricultural (rice paddies)	0.001	0.30	1.53	46%	Lamers et al. 2011
Imidacloprid	2003- 05	Central Florida, USA	Lakes	Agricultural (Citrus crops)	NA	ND	0.016	4%	Choquette and Kroening 2009
Imidacloprid	<200 4	California, USA	Surface waters	Agricultural	NA	ND	ND	NA	Fossen 2006

Chemical	Year	Location	Water body	Land use	Detection Limit (μg/L)	Mean concentration (μg/L)	Max Concentration (μg/L)	Detections	Source reference
Imidacloprid	2001	Florida, USA	NA	Agricultural	NA	ND	1	3%	Pfeuffer and Matson 2001 (in Fossen 2006)
lmidacloprid	2003- 05	New Brunswick, Canada	Runoff, streams	Potato fields	0.2	NA	0.3	NA	Hewitt 2006
Imidacloprid	2001- 02	Prince Edward Island, Canada	Runoff	Agricultural (Potato)	0.5	NA	11.9	NA	Denning et al 2004
Imidacloprid	2005- 07	Quebec, Canada	Rivers	Agricultural (Potato and vegetable)	0.001	1.26	7.8	100%	Gibeault-Delisle et al. 2010
Imidacloprid	2012	Quebec, Canada	Rivers	Agricultural (Potato)	NA	NA	7.7	NA	Giroux 2014 pers comm
Imidacloprid	2008	Sweden	Streams, rivers	Horticulture crops/ greenhouses	0.01	NA	15	36%	Kreuger et al 2010
lmidacloprid	1998, 2003- 09	Netherlands	Drainage ditches	Agricultural	NA	Most samples 0.013 – 1.6	320	NA	Van Dijk 2010 and Van Dijk et al. 2013
lmidacloprid	2013	Sydney, Australia	Rivers	Agricultural (vegetable and horticultural crops)	0.013	0.20 ± 1.17	4.56	93%	Sanchez-Bayo and Hyne 2014
lmidacloprid	2012- 13	Saskatchewan, Canada	Prairie wetlands	Agricultural (canola, cereals, grasslands)	0.0011	NA	0.25	0-8%	Main et al. 2014
lmidacloprid	2008- 12	Wisconsin, USA	Groundwater	Agricultural (potato, row crops)	NA	0.79	3.34	30%	State of Wisconsin Dept. of Agriculture Trade and Consumer Protection (in Huseth and Groves 2014)
Imidacloprid	2013	Iowa, USA	Rivers	Agricultural	0.0049	<0.002**	0.0427	23%	Hladlik et al. 2014
Imidacloprid	2009- 10	Massachusetts , USA	Rivers	Suburban	0.02	NA	6.9	15%	Wijnja et al. 2014
Thiamethoxam	2012	Switzerland	Rivers	Agricultural, urban areas, and WWTP discharges	0.003	NA	0.047	60%	Moschet et al. 2014

Chemical	·	Land use	Detection Limit (µg/L)	Mean concentration (μg/L)	Max Concentration (μg/L)	Detections	Source reference		
Thiamethoxam		Osaka, Japan		1	0.00063	0.00265	0.0011	100%	Yamamoto et al. 2012
Thiamethoxam	2012	Quebec, Canada	rivers Rivers	upstream Agricultural (Potato)	NA	NA	1.5	NA	Giroux 2014 pers comm
Thiamethoxam	2008	Sweden	Streams, rivers	Horticulture crops/ greenhouses	0.003	NA	0.16	3%	Kreuger et al 2010
Thiamethoxam	2005	Texas, USA	Playa wetlands	Agricultural (cotton)/ Grassland/	0.1	3.6	20.1/ 225	31%/ 25%	Anderson et al 2013
Thiamethoxam	2013	Sydney, Australia	Rivers	Agricultural (vegetable and horticultural crops)	0.014	0.10 ± 0.07	0.17	27%	Sanchez-Bayo and Hyne 2014
Thiamethoxam	2012- 13	Quebec, Canada	Ponded water on fields	Agricultural (corn)- during and post seeding	0.1	7.7	63.4	72–100%	Samson-Roberts et al (submitted)
Thiamethoxam	2012- 13	Saskatchewan, Canada	Prairie wetlands	Agricultural (canola, cereals, grasslands)	0.0018	0.004 – 0.077*	ND – 1.49	6-23%	Main et al. 2014
Thiamethoxam	2011- 12	Wisconsin, USA	Leachate (irrigation water/ground water)	Agricultural (potato, row crops- irrigated)	0.02	0.44 / NA	0.58/ >20.0	NA	Huseth and Groves 2014
Thiamethoxam	2008- 2012	Wisconsin, USA	Groundwater	Agricultural (potato, row crops)	NA	1.59	8.93	68%	State of Wisconsin Dept. of Agriculture Trade and Consumer Protection (in Huseth and Groves 2014)
Thiamethoxam	2013	Iowa, USA	Rivers	Agricultural	0.0039	<0.002**	0.185	47%	Hladlik et al. 2014

NA: not available; ND: not detected

^{*}Reported as total neonicotinoids. Author reports total as dominantly clothianidin and thiamethoxam.

^{**}Reported as the median, below method detection limit.

2.4. Terrestrial Exposures

2.4.1. Birds and Mammals

Terrestrial wildlife exposure estimates are typically calculated for birds and mammals by emphasizing the dietary exposure pathway. Thiamethoxam is applied through aerial and ground application methods, which includes sprayers, chemigation and soil drenching, as well as through seed treatments. Therefore, potential dietary exposure for terrestrial wildlife in this assessment is based on consumption of thiamethoxam residues on food items following spray (foliar or soil) applications, and from possible dietary ingestion of thiamethoxam residues on treated seeds. Rates used in modeling for spray and seed treatment applications are presented below in **Tables 18 and 19**.

Table 18. Application rates used for T-REX modeling for foliar and soil applications of thiamethoxam

Use	Application Type	Application Rate (lb a.i./A)	Number of Applications	Application Interval (days)	Maximum Annual (Ib a.i./A)
Agricultural	Foliar	0.086	1,2, or 3		0.258
Agricultural or non-agricultural	Soil	0.265	1	7	0.265

For treated seeds, the label lists all application rates in terms of lb a.i./A, while the T-REX modeling input value is in terms of fl oz/cwt. Different seed sizes and planting rates could result in ranges of exposure due to variability in the number of seed per acre. In order to account for seeding rates (included in T-REX and from USEPA 2011c), and seed size to get to that amount of a.i./A the application rates in terms of lbs a.i./cwt were calculated using the following equation:

Maximum application rate (fl oz/cwt) =

(maximum application rate (lb a.i./A) / (% a.i. in formulation/100)) * 128 fl oz/gal *100 lb seed/cwt maximum seeding rate (lb seed/A) 2 * product density (lb a.i./gal) 1

Table 19. Modeled Application Rates of Thiamethoxam Treated Seeds.

Crop	Product (EPA Reg.)	Application Rate (lb a.i./A) ¹	Application Rate (fl oz/cwt)	Seed Rate ²
Sugar Beet		0.167	188.3	4.8
Corn	Cruicar (100,041)3	0.113	20.7	29.6
Soy	Cruiser (100-941) ³	0.083	2.7	166.7
Cotton		0.071	20.3	18.9

¹ Based on input from BEAD; Value used in aquatic modeling

Foliar and Soil Application Exposure Estimates

EECs for birds and mammals via dietary residues resulting from foliar applications are presented below in **Tables 20-23** and were calculated using T-REX v.1.5.2. **Tables 20 and 22** represent EECs from agricultural uses at 1, 2, or 3 applications while **Tables 21 and 23** represent EECs from a single application for a non-agricultural use scenario. As mentioned in Problem Formulation **Section 1.2** these EECs are based on a streamlining strategy which considers past assessments and general low toxicity

² from USEPA, 2011c

³ 47.6% thiamethoxam; density = 10.5lbs/gal

relative to exposure values from the application of thiamethoxam. Estimated concentrations were calculated for the highest single and yearly foliar application rates to present an upper bound of thiamethoxam exposure potential from foliar application. EFED's default foliar dissipation rate of 35 days was used for this analysis to estimate dissipation after each application. Consideration of additional half-life values for characterization was not done based on the final EECs and subsequent LOC exceedances (or lack thereof) further explained in **Sections 4.1.4.1 and 4.1.4.2.** The default foliar dissipation half-life does only factors into calculated EECs for foliar applications. Upper-bound Kenaga nomogram values are used to derive EECs for thiamethoxam exposures to terrestrial mammals and birds (**Tables 20-23**). EECs presented encompass rates for all agricultural uses as well as non-agricultural uses (e.g. turf, Christmas trees).

EECs for soil applications (Tables 21 and 23) were calculated within T-REX using two methodologies: 1) the LD_{50}/ft^2 methodology and 2) considering arthropod residues (used to simulate exposures from foliar applications). Specifically, the information in Table 21 and 23 relevant to soil applications are those EECs on arthropods and the mg a.i./ft².

Conceptually, an LD_{50}/ft^2 is the amount of a pesticide estimated to kill 50% of exposed animals in each square foot of applied area. Although a square foot does not have defined ecological relevance, and any unit area could be used, risk presumably increases as the LD50/ft2 value increases. The LD_{50}/ft^2 value is calculated using a toxicity value (adjusted LD50) and the EEC (mg a.i./ft2) and is directly compared with the Agency's levels-of-concern (LOCs) for acute exposures. For thiamethoxam, a scenario resulting in the highest exposure (a broadcast application to a level field with no incorporation or consideration of existing furrows) was modeled using a single maximum application rate of 0.265 lb a.i./A which is consistent with the highest application rate to soil.

For the second method, exposure from soil application is estimated using the upper bound EECs in arthropods (also used for foliar applications). The residue values for the arthropod are used to represent potential exposures to birds and mammals that consume invertebrates that may be present on the field at the time of application. Arthropods were chosen because they are assumed to be present if the insecticide is being applied. Additionally, unlike, the LD_{50}/ft^2 methodology, this second methods allows for consideration of chronic exposures using the Kenaga values.

Table 20. Avian EECs Based on the Maximum Single Application Agricultural Rate of 0.086 lb. a.i./A.

				Dose Bas	ed EECs (r	ng/kg-bw)			Dietary Based EECs		
Food Items		Small (20	g)	M	Medium (100 g) Large (1000 g) (mg/kg				/kg-food i	tem)		
	1 app	2 apps	3 apps	1 app	2 apps	3 apps	1 app	2 apps	3 apps	1 app	2 apps	3 apps
Short Grass	23.5	44.0	61.8	13.4	25.1	35.2	6.0	11.2	15.8	20.6	38.6	54
Tall Grass	10.8	20.2	28.3	6.1	11.5	16.1	2.8	5.1	7.2	9.5	17.7	25
Broadleaf plants	13.2	24.7	34.8	7.5	14.1	19.8	13.2	24.7	34.8	11.6	21.7	31
Fruits/pods	1.5	2.7	3.9	1.5	2.7	3.9	0.4	0.7	1.0	1.3	2.4	3
Arthropods	9.2	17.2	24.2	5.3	9.8	13.8	2.4	4.4	6.2	8.1	15.1	21
Seeds	0.3	0.6	0.9	0.3	0.6	0.9	0.1	0.2	0.2	1.3	2.4	3

Table 21. Avian Dose Based EECs, Dietary Based EECs, and mg a.i./ft² based on the Single Highest Non-agricultural Use Application Rate of 0.265 lb a.i./A¹

FJ 14	Do	se Based EECs (mg/l	(g-bw)	Dietary Based EECs (mg/kg-	mg a.i./ft²	
Food Items	Small (20 g)	Medium (100 g)	Large (1000 g)	food item)	mg a.i./it-	
Short Grass	72.4	41.3	18.5	63.6		
Tall Grass	33.2	18.9	8.5	29.2		
Broadleaf plants	40.7	23.2	10.4	35.8	2.76	
Fruits/pods	4.5	2.6	1.2	4.0	2.76	
Arthropods	28.4	16.2	7.2	24.9		
Seeds	1.0	0.6	0.3	4.0		

¹This rate represents non-agricultural foliar use and agricultural soil uses. The EECs relevant to soil use patterns are those for arthropods and the mg a.i./ft²

Table 22. Mammalian EECs Based on the Maximum Single Application Agricultural Rate of 0.086 lb. a.i./A.

-					Dose Based EECs (mg/kg-bw)				Dietary Based EECs			
Food Items		Small (15	3)	N	tedium (35	5 g)	L	arge (1000	g)	(mg	(mg/kg-food item)	
	1 app	2 apps	3 apps	1 app	2 apps	3 apps	1 app	2 apps	3 apps	1 app	2 apps	3 apps
Short Grass	19.7	36.8	51.7	13.6	25.4	35.7	3.2	5.9	8.3	20.6	38.6	54.3
Tall Grass	9.0	16.9	23.7	6.2	11.7	16.4	1.4	2.7	3.8	9.5	17.7	24.9
Broadleaf plants	11.1	20.7	29.1	7.7	14.3	20.1	1.8	20.7	29.1	11.6	21.7	30.5
Fruits/pods	1.2	2.3	3.2	1.2	2.3	3.2	0.2	0.4	0.5	1.3	2.4	3.4
Arthropods	7.7	14.4	20.3	5.3	10.0	14.0	1.2	2.3	3.2	8.1	15.1	21.2
Seeds	0.3	0.5	0.7	0.3	0.5	0.7	0.0	0.1	0.1	1.3	2.4	3.4

Table 23. Mammalian Dose Based EECs, Dietary Based EECs, and mg a.i./ft² based on the Single Highest Non-agricultural Use Application Rate of 0.265 lb a.i./A¹

F114	Dos	se Based EECs (mg/	Dietary Based EECs (mg/kg-	: 1442	
Food Items	Small (15 g)	Medium (35 g)	Large (1000 g)	food item)	mg a.i./ft²
Short Grass	60.6	41.9	9.7	63.6	
Tall Grass	27.8	19.2	4.5	29.2	
Broadleaf plants	34.1	23.6	5.5	35.8	2.70
Fruits/pods	3.8	2.6	0.6	4.0	2.76
Arthropods	23.7	16.4	3.8	24.9	
Seeds	0.8	0.6	0.1	4.0	

¹This rate represents non-agricultural foliar use and agricultural soil uses. The EECs relevant to soil use patterns are those for arthropods and the mg a.i./ft²

Seed Treatment Exposure Estimates

EECs resulting from planting of thiamethoxam treated seeds are provided in **Tables 24 and 25** Results include Nagy dose-based values (*i.e.*, mg/kg-bw) and available mass of active ingredient per unit area (*i.e.*, mg a.i/ft²). Modeled scenarios were for three of the highest uses of thiamethoxam in treated seed which encompass a range of the foliar application rates (i.e. corn 0.113 lb a.i./A, soybean 0.083 lb. a.i./A, and cotton 0.071 lb a.i./A). Additionally, a seed treatment scenario was also run for smaller vegetable seeds (sugar beets) to be consistent with scenarios run in aquatic modeling. These rates considered were refined rates based on input from BEAD. Seed treatment exposure estimates are based not only on lb a.i. allowed per acre but how many seeds are planted. Fewer number of seeds planted per acre may increase dietary exposure due to more a.i. per unit of dietary item (the seed) available up to a maximum allowable poundage per acre.

Table 24. Avian Dose Based EECs and mg a.i./ft² EECs for Selected Thiamethoxam Treated Seed Uses

Crop	Small (20g)	Med (100g)	Large (1000g)	mg a.i./ft²
Sugar beet	8867	5053	2262	1.74
Corn	974	555	249	1.17
Soy	127	72	32	0.87
Cotton	955	545	244	0.74

Table 25. Mammalian Dose Based EECs and mg a.i./ft² EECs for Selected Thiamethoxam Treated Seed Uses

Crop	Small (15g)	Med (35g)	Large (1000g)	mg a.i./ft²
Sugar beet	7418	5127	1189	1.74
Corn	815	564	131	1.17
Soy	106	73	17	0.87
Cotton	800	553	128	0.74

2.4.2. Terrestrial Plants

Thiamethoxam exposure to terrestrial and semi-aquatic plants is estimated using the TerrPlant¹⁷ (version 1.2.2). The TerrPlant model generates EECs for plants residing near a use area that may be exposed via runoff and/or spray drift. The EECs are generated from one application at the maximum rate for a particular use and compound-specific solubility information. Only a single application is considered because it is assumed that for plants, toxic effects are likely to manifest shortly after the initial exposure and that subsequent exposures do not contribute to the response. The EECs for terrestrial and semi-aquatic (*i.e.*, wetland) plants for the maximum single foliar (ground) application of thiamethoxam to turf/ornamentals modeled at the rate of 0.265 lb a.i./A are presented in **Table 26** (only modeled ground as aerial not anticipated to be prevalent based on use pattern for turf).

Table 26. Terrestrial Plant EECs for Thiamethoxam. Units in lb a.i./A

Description	Equation	EEC							
1 applica	1 application at 0.265 lb a.i./A								
Runoff to dry areas	(A/I)*R	0.01325							
Runoff to semi-aquatic areas	(A/I)*R*10	0.1325							
Spray drift	A*D	0.00265							
Total for dry areas	((A/I)*R)+(A*D)	0.0159							
Total for semi-aquatic areas	((A/I)*R*10)+(A*D)	0.13515							

¹⁷ USEPA. 2013a. Pesticides: Science and Policy. Terrestrial Models, TerrPlant Version 1.2.2.

*Equation abbreviation: A – Application Rate; I – Incorporation; R – Runoff; and D – Drift Fraction N/A = Not applicable

3. Ecological Effects Characterization

In this preliminary ecological risk assessment, the effects characterization describes the types of effects thiamethoxam can produce in exposed organisms. This characterization is generally based on toxicity studies (registrant-submitted studies and open literature) that describe acute and chronic effects of thiamethoxam on aquatic or terrestrial animals and plants under controlled exposures in the laboratory

3.1. Aquatic Organisms (Fish, Aquatic Invertebrates, and Aquatic Plants)

A brief description of available aquatic toxicity data used to calculate RQs is provided in **Table 27**. Available toxicity data for aquatic organisms are summarized in this section.

Table 27. Summary of the Endpoints from Aquatic Toxicity Studies used to derive RQs for thiamethoxam

Study Type	Species	Toxicity Value (μg a.i./L)	Source (MRID) & Classification	Comment
Acute – Freshwater Fish ¹	Bluegill Sunfish (Lepomis machrochirus)	96-hr LC ₅₀ : >114,000	44714917 Acceptable	Limit test, no mortality or sub- lethal effects
Chronic (early life stage) – Freshwater Fish ¹	Rainbow Trout (Oncorhynchus mykiss)	NOAEC = 20,000	44714923 Supplemental	no effects observed at highest test concentration (i.e., 20 mg/L)
Acute – Estuarine/Marine Fish	Sheepshead minnow	96-hr LC ₅₀ : >111,000	44714920 Acceptable	no mortality or sublethal effects observed
Chronic (early life stage) – Estuarine/Marine Fish	(Cyprinodon variegatus)	NOAEC = 1700	49589511 Acceptable	5% decreased length at LOAEC of 4.1 mg a.i./L
Acute – Freshwater Invertebrate	Midge (Chironomus riparius)	48-h EC ₅₀ = 35	MRID 44714918 Acceptable	Water only exposure; Effect = immobility
Chronic – Freshwater Invertebrate		NOAEC = 0.74	Cavallaro et al. 2016 Quantitative	25% Decreased larval survival at 2.23 μg a.i./L
Acute — Estuarine/Marine Invertebrate	Mysid shrimp (Mysidopsis bahia)	96-hr LC ₅₀ =6900	44714922 Acceptable	None
Chronic — Estuarine/Marine Invertebrate		NOAEC = 1100	MRID 49589510 Acceptable	14% decrease in parent survival at LOAEC (2000 μg a.i./L)

Study Type	Species	Toxicity Value (μg a.i./L)	Source (MRID) & Classification	Comment
Acute Aquatic – Nonvascular Plants	Cyanobacteria (Skeletonema costatum)	96-hr IC ₅₀ : >99,000 NOAEC: 12,000	49346607 Acceptable	NOAEC based on decreased growth at LOAEC of 24,000 µg a.i./L
Aquatic – Vascular Plants	Duckweed (<i>Lemna gibba</i>)	7-day IC ₅₀ : >90,200 NOAEC: 22,000	44714925 Acceptable	NOAEC based on LOAEC of 43,900 µg a.i./L for phytotoxicity

¹ Freshwater fish acute and chronic toxicity data used as a surrogate for aquatic-phase amphibians.

Several studies (MRIDs 48432527-48432529) have been submitted with a formulated product containing thiamethoxam and cyantraniliprole (an insecticide). These studies are not discussed here.

In addition, a mesocosm study (MRID 50131101) involving thiamethoxam was submitted recently by the registrant. This study has not yet been reviewed by EFED.

3.1.1. Effects on Fish and Aquatic Phase Amphibians

Acute toxicity data are available for two species of freshwater fish and one estuarine/marine fish. Based on acute toxicity data for fish, thiamethoxam is characterized as practically non-toxic ($LC_{50} > 100 \text{ mg/L}$) on an acute exposure basis. In all three studies, no effects (including mortality or behavior) were observed at concentrations >109 mg a.i./L. In a chronic toxicity study with rainbow trout, no effects to survival or growth were observed at the highest test concentration of 20 mg a.i./L. In a chronic toxicity study with sheepshead minnow, a 5% decrease in length was observed at 4.1 mg a.i./L, resulting in a NOAEC of 1.7 mg a.i./L. No acute or chronic toxicity data available for aquatic-phase amphibians; therefore, available data for freshwater fish will be used to represent amphibians. No additional acute or chronic toxicity data for fish were identified in ECOTOX¹⁸. **Table 28** summarizes the available acute and chronic toxicity data available for fish exposed to thiamethoxam.

Table 28. Acute and Chronic Effects of Thiamethoxam on Fish

Species	Test material (% a.i.)	Endpoint (Duration)	Toxicity Value (95% CI; units: mg a.i./L)	Source	Classification
		Fres	shwater Fish		
Rainbow Trout Oncorhynchus mykiss	TGAI (98.6)	LC ₅₀ (96-hr)	>109	44714916	Supplemental (based on water source)/ Limit test; no effects observed
Rainbow Trout Oncorhynchus mykiss	TGAI (99.2%)	NOAEC (60 d)	20	44714923	Supplemental (because a LOAEC was not determined)/no effects (weight, length, survival) observed at highest test concentration (i.e., 20 mg/L)

¹⁸ This analysis focuses on apical endpoints (i.e., survival, growth or reproduction); open literature reporting non-apical endpoints were not considered.

Bluegill Sunfish Lepomis machrochirus	TGAI (99.2%)	LC ₅₀ (96-hr)	>114	44714917	Acceptable/ no mortality or sublethal effects observed
		Sal	twater Fish		
Sheepshead minnow Cyprinodon variegates	TGAI (99.2%)	LC ₅₀ (96-hr)	>111	44714920	Acceptable / no mortality or sublethal effects observed
Sheepshead minnow Cyprinodon variegates	TGAI (99.8%)	NOAEC LOAEC (33-d)	1.7 4.1	49589511	Acceptable/5.5% decreased length at LOAEC (4.1 mg a.i./L)

3.1.2. Toxicity to Aquatic Invertebrates

Toxicity data are available for several different Orders of aquatic invertebrates. Among the different Orders, aquatic insect species are more sensitive compared to other classes of arthropods or other phyla. The following discussion of thiamethoxam aquatic invertebrate toxicity data first focuses on non-insect taxa and then considers aquatic insects (e.g., Diptera). All registrant-submitted studies (acceptable or supplemental) are summarized here regardless if they produced the most sensitive endpoint for that species. For studies identified in the open literature, only those which produced the most sensitive endpoint for a given species and are classified as "quantitative" or "qualitative" are summarized in this section. This section focuses on apical endpoints, i.e., survival, growth and reproduction and those endpoints considered acute (i.e., 48-96 h EC₅₀ or LC₅₀) or chronic (NOAEC, LOAEC)

3.1.2.1. Acute toxicity to Freshwater Non-Insect Taxa

Relevant acute toxicity data on the effects of thiamethoxam to non-insect aquatic invertebrates for 4 freshwater species distributed among various orders (**Table 29**). A summary of these data by broad taxonomic group is provided below.

Amphipoda. Acute toxicity data (LC50s) for the amphipod *Gammarus kischineffensis* exposed to a formulated product containing thiamethoxam ranged from 3,750 μ g a.i./L for a 96 h exposure to 23,500 for 48 h.

Decapoda. Acute toxicity data are available from two studies for the same species of crayfish. In these studies, 96-h EC50 values ranged 967-2310 µg a.i./L.

Diplostraca. Available toxicity data for Daphnia magna, one of the most commonly tested aquatic invertebrate species, indicates that thiamethoxam is practically non-toxic to waterfleas. Only 15% immobility was observed at the limit concentration (i.e., 106,000 µg a.i./L).

Unionoida. In a study involving exposures to glochidia of wavy-rayed lampmussels, <50% mortality was observed after 48 h at 691 μ g a.i./L.

Table 29. Most sensitive acute toxicity data (registrant and open literature) for freshwater non-insects exposed to thiamethoxam

Species	Test material (% a.i.)	Endpoint (Duration)	Toxicity Value (95% CI; units: µg a.i./L)	Source	Classification
			Amphipod	da	
Amphipod	Actara	LC ₅₀ (48 h)	23,500	Ugurlu et al 2015;	Qualitative
(Gammarus	240SC	LC ₅₀ (72 h)	8,050	ECOTOX # 173084	
kischineffensis)	(24%)	LC ₅₀ (96 h)	3,750	_	
	•	· · · · · · · · · · · · · · · · · · ·	Decapod	a	•
Red swamp crayfish (Procambarus	TGAI (99.5)	LC ₅₀ (96 h)	967 (879- 1045)	Barbee and Stout 2009; ECOTOX # 120043	Qualitative
clarkia)	TGAI (98.4)	EC ₅₀ (96 h)	2310 (1630- 3280)	MRID 47558106	Supplemental (quantitative; classification based on non-standard test species)
			Diplostrac	ca	
Waterflea (Daphnia magna)	TGAI (98.6)	EC ₅₀ ** (48 h)	>106,000	MRID 44714919	Supplemental (water quality deviations from guideline; control contamination)
			Unionoid	a	
Wavy-rayed lampmussel (<i>Lampsilis</i> fasciola)	TGAI (>95)	LC ₅₀ (48 h)	>691	Prosser et al. 2016; ECOTOX # 173464	Qualitative

^{*}Immobility

3.1.2.2. Acute Toxicity to Freshwater Insect Taxa

Aquatic insects appear to be among the most sensitive aquatic invertebrate taxa to thiamethoxam. Acute toxicity data are available for two Orders of aquatic insects including: Diptera and Ephemeroptera. Collectively, the range of acute toxicity values varied from 20-343 μ g/L, which are generally more sensitive than the other tested aquatic invertebrates (toxicity data discussed above). **Table 30** summarizes the available acute toxicity endpoints for freshwater invertebrates (with 48-96 h median lethal endpoints and 50% effects concentrations).

Diptera (true flies). Toxicity data are available for one midge species (*Chironomus riparius*) and three species of mosquito (larval exposure). A 48-h EC_{50} of 35 μ g a.i./L for the midge is used quantitatively in this assessment; i.e., to derive RQs for acute exposures to aquatic invertebrates. Qualitative toxicity data suggest that mosquito larvae are as sensitive or less sensitive compared to midge.

Ephemeroptera (mayflies). Qualitative data are available for an acute exposure of one species of mayfly exposed to thiamethoxam. These data suggest that mayflies are of similar acute sensitivity to midge (EC50 values are within a factor of 2). Available mayfly data (Van Den Brink et al. 2016) are considered qualitative because they involved a formulated product and raw toxicity data are not available to verify the reported endpoints.

^{**} only 15% mortality observed at highest test level (i.e., 106,000 μ g/L)

Table 30. Most sensitive acute toxicity data (registrant and open literature) for freshwater insects exposed to thiamethoxam

Species	Test material (% a.i.)	Endpoint (Duration)	Toxicity Value (95% CI; units: μg a.i./L)	Source	Classification
			Diptera		
Midge	TGAI (97.4)	EC ₅₀ * (48 h)	35 (33-38)	MRID 44714918	Acceptable
(Chironomus riparius)	TGAI (99.6)	EC ₅₀ (48 h)	86.4 (74.4- 100)	Saraiva et al. 2017**	Qualitative
Mosquito	TGAI (99.1)	LC ₅₀ (72 h)	52	Uragayala et al. 2015;	Qualitative
(Anopheles stephensi)			ECOTOX #173152		
Mosquito (Aedes	TGAI (99.5)	LC ₅₀ (48 h)	130 (48-263)	Ahmed and	Qualitative
aegypti)		LC ₅₀ (72 h)	90 (29-190)	Matsumura 2012; ECOTOX #168249	
	TGAI (99.1)	LC ₅₀ (72 h)	298	Uragayala et al. 2015; ECOTOX #173152	Qualitative
Mosquito (Culex quinquefasciatus)	TGAI (99.1)	LC ₅₀ (72 h)	343	Uragayala et al. 2015; ECOTOX #173152	Qualitative
		E	phemeroptera		
Mayfly (Cloeon dipterum)	Formulated (25)	EC ₅₀ * (96 h)	20 (15-26)	Van Den Brink et al. 2016; ECOTOX#173151	Qualitative

^{*}Based on immobility

3.1.2.3. Acute Toxicity to Saltwater Aquatic Invertebrates

Two acceptable registrant-submitted studies are available including the mysid shrimp and the Eastern oyster which both tested TGAI (**Table 31**). In the acute mysid shrimp (*Mysidopsis bahia*) study, the 96-hr LC_{50} value was 6900 μ g a.i./L. In the oyster study (*Crassostrea virginica*), the 96hr EC_{50} , based on shell deposition, was >119,000 μ g a.i./L. no additional acute toxicity data involving saltwater invertebrates were identified in ECOTOX.

Table 31. Acute toxicity data for estuarine/marine invertebrates exposed to thiamethoxam

Species	Test material (% a.i.)	Endpoint (Duration)	Toxicity Value (95% CI; units: μg a.i./L)	Source	Classification
Mysid shrimp (Mysidopsis bahia)	TGAI (99.2)	LC50 (96 h)	6900 (5800- 8400)	MRID 44714922	Acceptable
Eastern oyster (Crassostrea virginica)	TGAI (99.2)	EC50* (96 h)	>119,000	MRID 44714921	Acceptable

^{*}Effect based on decreased shell deposition; 13% decrease in shell deposition observed at 119,000 µg/L

3.1.2.4. Chronic Toxicity to Freshwater and Saltwater invertebrates

^{**}Sand included in test vessels

Chronic toxicity data are available for five different aquatic invertebrate species including: mayflies, midges, waterfleas, and mysid shrimp. Studies are available where organisms were exposed through water only, as well as through sediment (**Tables 32 and 33**). As observed with the acute toxicity data above, tested aquatic insect species are more sensitive compared to other invertebrate species (e.g., water flea and mysid shrimp).

Table 32. Chronic toxicity data for freshwater and estuarine/marine invertebrates exposed to thiamethoxam in water. Studies involve non-insect taxa.

Species	Test material (% a.i.)	Endpoint (Duration)	Toxicity Value (effects observed; units: µg a.i./L)	Source	Classification
Mayfly (Cloeon dipterum)	Formulated (25)	EC ₁₀ (28 d)	0.43 (95% CI: 0.13- 1.4; immobility)	Van Den Brink et al. 2016; ECOTOX#173151	Qualitative
Midge (Chironomus dilutus)	TGAI (98.9)	NOAEC LOAEC (14 d)	0.74 2.23 (25% decreased larval survival)	Cavallaro et al. 2016*	Quantitative
Midge (C. riparius)	TGAI (99.6)	NOAEC LOAEC (28 d)	6.5 10.5 (65% decreased emergence; no females emerged at LOAEC)	Saraiva et al. 2017*	Qualitative
Midge (C. riparius)	TGAI (99.6)	NOAEC LOAEC (10 d)	10.5 18 (decreased survival and length)	Saraiva et al. 2017*	Qualitative
Mysid shrimp (<i>Mysidopsis</i> bahia)	TGAI (99.8)	NOAEC LOAEC (28 d)	1100 2000 (14% decrease in parent survival)	MRID 49589510	Acceptable
Waterflea (Daphnia magna)	TGAI (98.6)	NOAEC LOAEC (21 d)	50,000 101,000 (LOAEC based on 16% decreased #offspring)	MRID 44714924	Acceptable

^{*}Concentrations expressed as overlying water assumed to be comparable to pore water concentrations because 1) thiamethoxam has a low Koc value (it is expected that pore water and overlying water will be very similar at equilibrium); 2) there is a *de minimus* amount of organic carbon in the sand matrix used in this study (sorption to the solid portion of the benthic layer is not expected to be substantial) and 3) the coarse particle size of the sand facilitates exchange between the overlying water and pore water, allowing for equilibrium to occur within a short period of time

Table 33. Chronic toxicity data for freshwater and estuarine/marine invertebrates exposed to thiamethoxam via sediment; concentrations expressed on a pore water basis.

Species	Test material (% a.i.)	Endpoint (Duration)	Toxicity Value (effects observed; units: µg a.i./L pore water)	Chemical introduced through water (overlying) or sediment	Source	Classification
Midge (Chironomus riparius)	TGAI (98.6)	NOAEC LOAEC (30 d)	<1 (LOD)* 6	sediment	MRID 44714928	Under review
Midge (C. riparius)	TGAI (98.6)	NOAEC LOAEC (30 d)	10* 20 (decreased emergence)	water	MRID 44714928	Under review
Midge (C. dilutus)	TGAI (99.8)	NOAEC LOAEC (10 d)	120 360 (LOAEC based on 19% reduced weight)	sediment	MRID 49589512	Acceptable

^{*}Study author reported results.

Data published by Cavallaro et al. (2016) is used to derive chronic RQs for aquatic invertebrates. The LOAEC calculated by EFED using the study author's raw data was 2.23 ug a.i./L. At this level, a 25% decline in larval survival was observed. Therefore, the NOEC is 0.71 ug a.i./L.

Other studies are also available for *Chironomus* species exposed to thiamethoxam. Table 34 summarizes the LOECs for the different endpoints measured in each of the studies involving *Chironomus* species. Saraiva et al. (2017) observed effects at a level that was a factor of 2-8x higher compared to Cavallaro et al. This difference in effect may be attributed to shorter observation periods (i.e., shorter observation periods usually yield less sensitive endpoints) and to a difference in observed endpoints. Sediment toxicity studies (MRID 44714928) showed effects to adult emergence in 30 d studies where *Chironomus* species were exposed to 6 or 9 ug a.i./L in pore water. This is similar to the level where effects to adult emergence was observed by Cavallaro et al. 2015. In a 10 d study (MRID 49589512), effects to larval survival and growth growth were observed at 360 ug a.i./L in pore water. Effects observed at an order of magnitude higher than other studies can likely be attributed to the shorter duration of this study.

Table 34. Summary of LOEC values (and observed declines relative to controls) from studies involving *Chironomus sp.*

Study D	Test design			or pore water; per ve to control)	cent
		Larval survival	Larval growth	adult emergence	Adult body weight

Cavallaro et	40	Thia. spiked through	2.23 (25%)	NA	5.7 (69%)	NA
al. (2016)		water; sand as sediment				
Saraiva et	28	Thia. spiked through	18 (44.5)	18	10.5 (84%)	NA
al. (2017)		water; sand as sediment		(~20%)**		
MRID	30	Thia. spiked through	NA	NA	9 (100%)	NA
44714928		water; artificial sediment				
MRID	30	Thia. spiked through	NA	NA	6 (100%)	NA
44714928		sediment; artificial				
		sediment				
MRID	10	Thia. spiked through	360 (10%)	360 (19%)*	NA	NA
49589512		water; artificial sediment				

NA = not available (endpoint not included in study or significant effects not observed)

A 28-d study by Van Den Brink et al. (2016) reported LC10 and LC50 values of 0.81 and 0.94 ug a.i./L (respectively) for mayfly larvae exposed to thiamethoxam (as a formulated product). The LC10 and LC50 values are a factor of 2.8 and 2.4 (respectively) lower than the LOEC from Cavallaro et al. (2016) where 25% mortality was observed in *Chironomus* sp. (i.e., 2.23 ug a.i./L). These comparisons suggest that the tested mayfly species is of similar sensitivity to tested *Chironomus sp*.

3.1.2.5. Aquatic Plant Toxicity Data

 EC_{50} values for aquatic plants were not established, with <50% effects observed at concentrations 90 mg a.i./L and higher. Significant effects to growth were observed in the most sensitive non vascular species at 24 mg a.i./L. No aquatic plant toxicity data were identified in ECOTOX. **Table 34** summarizes the available plant toxicity data for thiamethoxam.

Table 34. Summary of available aquatic plant toxicity data for thiamethoxam.

Species (% a.i.)	Endpoint (Duration)	Toxicity Value (mg a.i./L)	MRID	Study Classification / Comment
	Α	quatic Vascular Pla	nts	
Duckweed (<i>Lemna</i> gibba) (TGAI, 98.6%)	7-d EC ₅₀ 7-d NOAEC	>90.2 22	MRID 44714925	Acceptable / no effects to frond # at 90.2 mg/L; NOAEC based on phytotoxicity observed at 43.9 mg/L
	Aq	uatic Nonvascular P	lants	
Saltwater diatom (Skeletonema costatum) (TGAI, 99.8%)	96-hr EC ₅₀ NOAEC	>99 12	MRID 49346607	Supplemental / LOAEC = 24 mg a.i./L (17% decline in area under the curve)
Cyanobacteria (Anabaena flos- aquae) (TGAI, 99.8%)	96-hr EC ₅₀ NOAEC	105 47	MRID 49346605	Supplemental / LOAEC = 97 mg a.i./L (44% decline in cell density)

^{*}measured as dry weight

^{**}measured as length

Green Algae	96-hr EC ₅₀	>97	MRID 44714926	Acceptable / no
Selenastrum	NOAEC	97		effects to biomass
capricornutum				observed
(TGAI, 98.6%)				
Freshwater diatom	96-hr EC ₅₀	>98	MRID 49346606	Supplemental
(Navicula	NOAEC	98		(qualitative) / no
pelliculosa)				effects to growth
(TGAI, 99.8%)				observed

3.2. Effects to Terrestrial Organisms (Birds, Mammals, and Terrestrial Plants)

Tables 35 and 36 summarize the most sensitive terrestrial toxicity data used for risk estimation of thiamethoxam based on an evaluation of submitted studies and available open literature. In general, thiamethoxam is characterized as slightly toxic to birds on an acute oral exposure basis and practically non-toxic on a subacute dietary exposure basis. The most sensitive avian species is the mallard duck for both acute and chronic exposures. With respect to mammals, thiamethoxam is considered slightly toxic on an acute oral basis. Generally minimal effects are seen in plant studies where exposures were at max application rates. Additional information on effects seen in the toxicity studies is presented below.

Table 35. Summary of the Endpoints from terrestrial Toxicity Studies used to derive RQs for thiamethoxam

Taxonomic Group	Study Type (% a.i.)	Species	Toxicity Value	Acute Toxicity Category	Source and Classification
Birds (reptiles and terrestrial phase amphibians)	Acute – Avian Oral 850.2100 (98.6%)	Mallard Duck (Anas platyrhynchos)	LD ₅₀ : 576 mg/kg- bw/day NOAEC: Not determined	Slightly toxic	44703307 Acceptable
	Acute – Avian Dietary 850.2200 (98.6%)	Mallard Duck (Anas platyrhynchos)	LC ₅₀ : >5200 mg/kg- diet NOAEC: 1300 mg/kg- diet	Practically non- toxic	44703310 Acceptable
	Chronic – Avian Reproduction 850.2300 (98.3%)	Mallard Duck (Anas platyrhynchos)	NOAEC: 300 mg/kg-diet LOAEC: 900 mg/kg-diet (weight loss in parental males)		44703311 Acceptable
Mammals	Acute – Mammalian Oral 870.1100 (98.6%)	Rat (Rattus norvegicus)	LD ₅₀ : 1563 mg/kg-bw	Slightly toxic	44703314

Chronic – Mammalian Reproduction 870.3800 (98.6%)	Rat (Rattus norvegicus)	NOAEL: 61 mg/kg-bw/day LOAEL: 158 mg/kg bw/day (reduced body weight gain in offspring during lactation period)		44718707
---	----------------------------	---	--	----------

Table 36. Terrestrial Plant toxicity

Taxonomic Group	Study Type (% a.i.)	Species	Toxicity Value	Source and Classification
Terrestrial Plants	Vegetative Vigor 850.4150 (24.9%)		$\frac{\text{Monocot:}}{\text{EC}_{25}/\text{IC}_{25}: > 0.28 \text{ lb a.i/A}}$ $\text{NOAEC: 0.28 lb a.i/A}$ No effects $\frac{\text{Dicot}}{\text{EC}_{25}/\text{IC}_{25}: > 0.28 \text{ lb a.i/A}}$ $\text{NOAEC: 0.061 lb a.i/A}$ $\text{Based on: Oilseed rape - Height}$	49105801
	Seedling emergence 850.4100 (24.9%)	Multiple	$\frac{\text{Monocot:}}{\text{EC}_{25}/\text{IC}_{25}:} > 0.28 \text{ lb a.i/A}$ $\text{NOAEC: } 0.28 \text{ lb a.i/A}$ No effects $\frac{\text{Dicot:}}{\text{EC}_{05}/\text{IC}_{05}} = \text{NC (unreasonable C.I.)}$ $\text{EC}_{25}/\text{IC}_{25}: 0.028 \text{ lb a.i/A}$ $(95\% \text{ C.I.: } 0.0025\text{-}0.23 \text{ lb a.i/A})$ $\text{NOAEC: } < 0.017 \text{ lb a.i/A}$ $\text{Endpoint based on cucumber shoot length (height)}$	49108701

3.2.1. Acute, Sub-Acute, and Chronic Effects on Birds

Additional studies submitted for avian toxicity (which were less sensitive) are included below in **Table 37.**

Table 37. Summary of the Additional Avian Endpoints from Submitted Toxicity Studies for Thiamethoxam

Study Type (% a.i.)	Species	Toxicity Value	Acute Toxicity Category	Source and Classification
Acute – Avian Oral 850.2100 (98.6%)	Bobwhite Quail (Colinus virginianus)	LD ₅₀ : 1552 mg/kg-bw/day NOAEC: 125 mg/kg- bw/day	Slightly toxic	447033-07 Acceptable

Study Type (% a.i.)	Species	Toxicity Value	Acute Toxicity Category	Source and Classification
Acute – Avian Dietary 850.2200 (98.6%)	Bobwhite Quail (Colinus virginianus)	LC ₅₀ : >5200 mg/kg-diet NOAEC: 2600 mg/kg-diet	Practically non- toxic	447033-09 Acceptable
Chronic – Avian Reproduction 850.2300 (98.3%)	Bobwhite Quail (Colinus virginianus)	NOAEC: 900 mg/kg-diet LOAEC: >900 mg/kg-diet (reduced egg size)	N/A	447033-12 Acceptable

In an acute toxicity study with the mallard duck the 14-day LD $_{50}$ was 576 mg a.i./kg bw with sub-lethal effects observed including vomiting, lethargy, unsteadiness, and inability to stand. There was a reduction in feed consumption and body weights in treated birds as compared to the controls. Vomiting birds were observed at all treatment levels, although the study report was unclear if this was regurgitation directly after dosing or later in the study. While for the bobwhite quail the 21-day LD $_{50}$ was 1552 mg a.i./kg-bw with observed sublethal effects observed including unsteadiness, lethargy, ruffled feathers and morbidity. There was also a reduction in feed consumption and body weights in treated birds as compared to the controls. The NOEL for mortality and clinical signs was 125 mg a.i./kg body weight. Two studies with passerines have been submitted to the agency conducted under the OECD TG223¹⁹ one (MRID 49025801) was classified as invalid due to unavailable background mortality in birds (wild sparrows) used leading to uncertainties if effects are attributable to thiamethoxam. The other (MRID 49755701), is still under review by the Agency. This test had regurgitation in several of the test doses. The study authors analysis determined an LD $_{50}$ value to be 431 mg/kg-bw based on mortality (not regurgitation) as all regurgitating birds died. Note: This endpoint is less sensitive than the LD $_{50}$ used in the assessment for small birds based on a scaled value from the mallard duck endpoint.

There were no mortalities in dietary ($LC_{50}>5200$ mg a.i./kg-diet) tests for either the mallard or the bobwhite. Decreased body weight was the only sub-lethal effect seen (in the 2600 mg a.i./kg diet and 5200 mg a.i./kg diet treatment groups) for the bobwhite quail, while the mallard exhibited a reduction in both feed consumption and body weight gain (in the 1300 mg a.i./kg diet and higher dose levels). Additionally, a slight reduction in feed consumption was noted in birds at 325 mg a.i./kg diet and 650 mg a.i./kg diet treatment levels so the NOAEC was determined to be 163 mg a.i./kg diet.

There were no significant treatment-related effects on mortality, clinical symptoms, feed consumption or body weights at the dietary levels of thiamethoxam used in the reproductive effects test on the bobwhite quail. However, six mortalities (adults) occurred and were attributed to pair aggression, getting caught in the caging, and euthanization (based on an inability to walk). The NOAEC for reproductive effects was determined to be 900 mg a.i./kg diet (the highest dose tested). There were no significant treatment-related effects on adult mortality in the reproductive effects test on the mallard duck. Pathological examination of the one mortality during Week 15 in the 100 mg a.i./kg diet treatment group revealed blocked and infected intestines and emaciation. There was a significant reduction in body weights noted for males in the highest dose group as compared to the controls; females were not affected. There were no reproductive effects at any treatment level. The NOAEC based on weight loss in parental males was determined to be 300 mg a.i./kg diet.

62

¹⁹ Agency guidance for considering TG223 studies as valid for risk assessments can be found here: https://www.epa.gov/pesticide-science-and-assessing-pesticide-risks/guidance-classifying-studies-conducted-using-oecd

3.2.1.1. Other Avian Studies

The American Bird Conservancy (ABC) commissioned a report²⁰ (released in 2013), "The Impact of the Nation's Most Widely Used Insecticides on Birds," reviewing 200 studies on neonicotinoids including industry research obtained through the US. Thiamethoxam is considered in this report along with other neonicotinoids including clothianidin and imidacloprid. No additional thiamethoxam toxicity data was in the ABC report outside of what is reported above. The ABC report's methods on how those data are used to evaluate risks was considered but ultimately determined not sufficiently robust for use in this assessment at this time for thiamethoxam. While data are available for the standard Agency test species (bobwhite quail and mallard duck) exposed to thiamethoxam through acute oral doses, several of these endpoints are non-definitive. As such, at this time, there are insufficient data to derive a species sensitivity distribution which could be used to estimate risk and further characterize the toxicity of thiamethoxam to birds. Regarding, methodological differences in data usage (e.g. SSDs in the ABC report), this assessment does address and refine concerns alluded to for effects on avian species consuming treated seeds.

3.2.2. Acute and Chronic Effects on Mammals

In the oral toxicity test with the rat, all observed mortalities (in each sex) in the 1500 (3), 2300 (4), 3800 (5) and 6000 (5) mg/kg-bw groups occurred within 6 hours of treatment. Clinical signs included ptosis (all doses), decrease in spontaneous movement and tonic convulsion (1500 mg/kg bw and above). The surviving animals returned to normal on the day following dosing. Reduced body weight gain was observed in all treated animals for the first two days following dosing.

In the 2-generation reproduction study, body weight gain (parents) was slightly lower in the 2500 ppm group during the first 6 weeks of the study, and F_0 and F_1 generations, in males only. However, the effect was marginal and was not considered to be toxicologically significant. Decreased testis weight was observed in the F_1 generation at 2500 ppm, and increased incidence and severity of tubular atrophy was observed in the testes in the F_1 generation at 30 ppm and above. Sperm motility was decreased in all treatment groups in both generations; however, there was no dose-response relationship. There was high variability among all groups and there were no treatment-related effects on sperm count or sperm morphology. A special investigation into the effects on sperm, concluded the initial findings were likely due to technical error and not treatment related. The supplemental information was limited to analysis of F_0 animals, hence no information relevant to the findings in F_1 animals is available. There were no other adverse, treatment-related effects on reproductive parameters (mating, gestation, fertility, viability) noted at any dose level tested for the parents.

For offspring, body weight gain was lower in the 2500 ppm group during the lactation period in the F_{1a} , F_{1b} , F_{2a} and F_{2b} litters, both sexes, resulting in lower body weights on days 7, 14 and/or 21 postpartum. Slightly lower body weight gains and body weights (days 7, 14 and/or 21 postpartum) were also noted in the 1000 ppm group for F_{2a} and F_{2b} females. However, the effect was marginal (\leq 8% lower than the control group values), F_{1a} and F_{1b} pups were not affected and males were not affected, and so this finding was not considered to be toxicologically significant. Based on reduced body weight gain during the lactation period in all litters, the NOAEL was determined to be 1000 ppm (61 mg/kg bw/day in males and 79 mg/kg bw/day in females).

-

²⁰ https://abcbirds.org/article/birds-bees-and-aquatic-life-threatened-by-gross-underestimate-of-toxicity-of-worlds-most-widely-used-pesticide-2/

3.2.3. Terrestrial Plant Toxicity Data

In a vegetative vigor test (maximum rate tested: 0.26 lb a.i/A), oilseed rape (dicot) was the only species to exhibit biologically meaningful effects (height). For soybean, a statistically significant reduction of 22% was detected for weight at the 0.033 lb a.i./A test level. While for sugar beet a statistically significant reduction of 12% was observed for height at the highest test level. However, the inhibitions at the test levels above and below fluctuated for these test crops, effects did not demonstrate a dose response relationship, and there was a significant lack of fit to the regression model. Consequently, EC₂₅ values were not generated because effects greater than 25% were not seen. None of the other species showed effects.

In the seedling emergence test (maximum rate tested: 0.26 lb a.i/A) the % inhibition in seedling emergence in the treated species as compared to the control ranged from -3 to 25%. The most sensitive monocot species could not be determined as there was a lack of statistically significant reductions that culminated in a dose response relationship. The most sensitive dicot species was cucumber, based on reductions in height ranging from 20.9-32.9% (lowest-highest test concentrations), resulting in NOAEC and EC₂₅ values of <0.017 and 0.028 lb a.i./A, respectively²¹. Based on these results another seedling emergence test was run with cucumber (MRID 50131103) to establish a NOAEC. The results of this study are still under review by the agency. Taken at face value results of this study showed no effects > 25% reduction of emergence, survival, length or weight, yielding an EC₂₅, NOAEC and LOAEC values (nominal concentration) of > 0.265, 0.265, and >0.265 lb a.i./A respectively.

Additionally, emergence and survival were significantly affected in onion and oilseed rape. However, these effects were determined not to be treatment related. For survival and emergence in onion, a statistically significant reduction was detected at the 0.033 lb a.i./A (only) test level, where inhibition was 25%. The other test levels showed promotion of emergence. For survival and emergence in oilseed rape a statistically significant reduction was only detected at the lowest test level, where inhibition was 24%. There was promotion of emergence, no emergence, or a 3% reduction in emergence in the remaining test levels. In both species, there was significant lack of fit reported for the linear regression analysis, and 95% confidence intervals could not be calculated. According to the reviewer's best professional judgment, the NOAEC was determined to be 0.28 lb a.i./A as none of the effects observed appeared to be treatment related and were not dose responsive.

3.3. Review of Incident Data

The Office of Pesticide Programs (OPP) maintains a database called the Incident Database System (IDS) in which wildlife incidents reported to the Agency from a variety of sources are maintained. For some of these incidents in IDS, a narrative of an incident is available and report information such as magnitude of the number of organisms impacted, location, date, product used, use pattern, whether the use was a registered use, and any confirmatory residue analysis if available. The sources of information for incidents include, registrant reports submitted under the Federal Insecticides, Fungicides, and Rodenticides Act (FIFRA) §6(a)(2) reporting requirement, as well as reports from local, state, national and international-level government reports on bee kill incidents, news articles, and correspondence made to EFED by phone or via email.

²¹ Significant reductions in weight were also found; however the effects were not dose responsive and ranged from -5.54% in the second highest test level to 24.7% in the second lowest test level.

It is noted that not all reported incidents are associated with narrative or analytical information that definitively links thiamethoxam to the affected species. Analytical information can include residue analysis to confirm if thiamethoxam is present. Even in those cases, many incident reports are associated with findings of other pesticides, of which the interactions with thiamethoxam in contributing to potentially enhanced sensitivity for the affected entity are not fully understood. In other instances, thiamethoxam may only be suspected to be the cause of based on available observational data. This is not always supported by a confirmatory residue analysis. Typically, the reported wildlife incidents serve as a line of evidence in determining the potential effects of thiamethoxam, as the reports are useful in understanding how these chemicals may impact organisms under the actual use conditions. Much of the incident information made through phone and email correspondence to EFED does not usually include a thorough investigation of the incident or provide any confirmatory residue data to link a chemical with a particular incident. Rather, much of these reports are anecdotal in nature. A search of these databases in June of 2017 yielded 4 incidents for non-pollinator taxa. These identified incident are summarized below in **Table 38**.

Additional incidents (to those in IDS) are reported to the Agency in aggregated form. Pesticide registrants report certain types of incidents to the Agency as aggregate counts of incidents occurring per product per quarter. Ecological incidents reported in aggregate reports include those categorized as 'minor fish and wildlife' (W-B), 'minor plant' (P-B), and 'other non-target' (ONT) incidents. 'Other non-target' incidents include reports of adverse effects to insects and other terrestrial invertebrates.

Table 38. Summary of Terrestrial Plant and Animal incidents for Thiamethoxam

Incident						Legality	Certainty
ID	County	State	Magnitude	Year	Description		
1023444-	Stearns	MN	100% of	2011	Plant: In Stearns County, MN	Undetermined	Abamectin:
001			285 Acres		one hundred percent of 285		Possible
					acres of treated corn		
					experienced stand issues after a		Thiamethoxam
					diluted application of the		: Possible
					product Avicta Duo (a.i.		
					abamectin, thiamethoxam).		
1022450-	Buffalo	NE	50% of 80	2009	Plant: In Buffalo County, NE the	Undetermined	Metalaxyl-M:
009			Acres		product CruiserMaxx Beans was		Possible
					applied as a seed treatment to		
					80 acres of soybeans injuring		Fludioxonil:
					50% of the crop. CruiserMaxx		Possible
					Beans contains the active		
					ingredients thiamethoxam,		Thiamethoxam
					fludioxonil and mefenoxam.		: Possible
1024031-	Hensel	Ontario	2 birds	2012	Avian: On April 12, 2012 in	Undetermined	Clothianidin:
003					Hensel, Ontario, Canada a bee		Possible
					keeper reported chemical drifts		
					from an air seeder used to plant		Thiamethoxam
					corn. Corn field is about 75 feet		: Possible
					north of bee yard. It was		
					reported that mostly Pioneer		
					(a.i. thiamethoxam) and some		
					Dekalb (a.i. clothianidin) were		
					applied. Talc powder was added		
					to the seed. No wind at the time		

Incident						Legality	Certainty
ID	County	State	Magnitude	Year	Description		
					of planting and the temperature		
					was around freezing. Samples		
					were collected on April 17, 2012		
					by Health Canada Management		
					Program were sent for analyzes.		
					a dead robin was reported found		
					on April 25,2012 and then a		
					dead flycatcher a few days later.		
					No laboratory analysis has been		
					submitted on the dead bees or		
					birds.		
1025475-	Yakima	WA	Not	2002	Plant: On or about June 6, 2013	Registered use	Thiamethoxam
001			reported		the following was reported to		: Possible
					DuPont: in the late spring		
					Fontelis (a.i. penthiopyrad) was		Note multiple
					applied in a large mixture of		other a.i. (10)
					other products, including		products
					thinners, adjuvants, and plant		present in
					growth regulators. This allegedly		incident
ı					caused leaves to burn/speckle		package.
					and the fruit to thin.		

4. Risk Characterization

Risk characterization provides the final step in the risk assessment process. In this step, exposure and effects characterizations are integrated to provide an estimate of risk (i.e., Risk Quotient) relative to established levels of concern (LOCs; Section 5.1). The results are then interpreted through a risk description that considers multiple lines of evidences and an overall conclusion (Section 5.2). In addition, the risk description also contains a discussion of relevant sources of uncertainty in the risk assessment and sensitivity of the risk assessment findings to important methodological assumptions.

4.1. Risk Estimation – Integration of Exposure and Effects Data

As discussed in the problem formulation, risk characterization integrates EECs and toxicity estimates and evaluates the likelihood of adverse ecological effects to non-target species. For thiamethoxam, a deterministic approach is used to evaluate the likelihood of adverse ecological effects to non-target species. In this approach, RQs are calculated by dividing EECs by the lowest acceptable/quantitative acute and chronic toxicity endpoints for non-target species (i.e., Risk Quotient (RQ) = Exposure Estimate/Toxicity Estimate).

RQs are then compared to LOCs. These LOCs are criteria used to indicate potential risk to non-target organisms and the need to consider regulatory action. Exceeding an LOC is interpreted to mean that the labeled use of the pesticide has the potential to cause adverse effects on non-target organisms (USEPA 2004).

4.1.1. Risk to Fish and Aquatic Phase Amphibians

The acute and chronic RQs for fish did not exceed the acute or chronic LOC for all thiamethoxam uses (RQs \leq 0.002). The highest RQs resulted from PWC and PFAM are presented in **Table 39**. Although the acute toxicity values for both freshwater and estuarine/marine fish were non-definitive (LC₅₀ > limit concentration), RQs were calculated assuming this non-definitive value was the LC₅₀ value. Therefore, actual acute RQs would be less than those presented, which are already at least an order of magnitude below the lowest LOC (i.e., 0.05). Additionally, fish were surrogates for aquatic-phase amphibians.

Table 39. Maximum acute and Chronic RQs for fish exposed to thiamethoxam. EECs generated using PWC.

Model	App method	Use	S
PWC	Foliar (aerial)	Forestry	N
PFAM	Seed	Rice (seed)	С

^{*}Based on 1 d EEC and 96-hr LC₅₀: >114,000 µg a.i./L (MRID 44714917)

4.1.2. Risk to Aquatic Plants

The RQs for aquatic vascular and non-vascular plants did not exceed the LOC (1) for all thiamethoxam uses (RQs <0.001). **Table 40** depicts the RQs based on the highest 1-d EEC generated by PWC and PFAM. Although the IC_{50} toxicity values for aquatic plants were non-definitive (IC_{50} > highest concentration tested), RQs were calculated assuming this non-definitive value was the IC_{50} value. Therefore, actual RQs would be less than those presented.

Table 40. Maximum RQs for aquatic plants exposed to thiamethoxam. EECs generated using PWC.

Model	App method	Use	Scenario	1-day EEC (μg a.i./L)	Listed vascular RQ*	Non-listed vascular RQ**	Listed non- vascular RQ***	Non- listed non- vascular RQ****
PWC	Foliar (aerial)	Forestry	NC apple	5.82	<0.001	<0.001	<0.001	<0.001
PFAM	Seed	Rice (seed)	CA rice	66.4	0.006	0.003	0.001	0.001

^{*}Based on 1 d EEC and 7-d NOAEC = $22,000 \mu g a.i./L (MRID 44714925)$

4.1.3. Risk to Aquatic Invertebrates

As presented in **Tables 41-43**, for thiamethoxam uses with foliar, soil and seed treatments, there was one non-listed acute LOC freshwater (FW) exceedance, based on seed treatments to rice. No other uses resulted in RQs that exceeded the acute LOC for non-listed species (i.e., RQ<0.5). For foliar and soil treatments, the acute listed LOC (0.05) was exceeded for the majority of uses for freshwater (FW) invertebrates. For seed treatments, only use on rice exceed the listed species LOC for freshwater invertebrates.

^{**} Based on 60 d EEC and NOAEC = 1700 μ g a.i./L (MRID 49589511)

^{***} Based on 60 d EEC and NOAEC = 20,000 µg a.i./L (MRID 44714923)

^{**}Based on 1 d EEC and 7-d IC₅₀: >90,200 μg a.i./L (MRID 44714925)

^{***}Based on 1 d EEC and 96-hr NOAEC = 12,000 μg a.i./L (MRID 49346607)

^{****}Based on 1 d EEC and 96-hr IC_{50} : >99,000 µg a.i./L (MRID 49346607)

The chronic LOC (1.0) was exceeded for FW invertebrates for all foliar and soil uses, except cranberry. For seed treatments, all modeled uses resulted in RQs below the chronic LOC, except rice. Because of the seed planting depth>2 cm for some crops (i.e., corn and wheat), EECs and resulting RQs were 0, resulting in no LOC exceedances.

None of the saltwater (SW) invertebrate acute or chronic RQs exceeded the non-listed or listed species LOCs.

Table 41. Foliar applications: Summary of Acute and Chronic RQs for Freshwater (FW) and saltwater (SW) Invertebrates.

-			EEC (με	; a.i./L)	RQ			
App method	Use	Scenario	1-day	21- day	FW Invert Acute ¹	SW invert	FW Invert	SW Invert
	Cotton	MS cotton	3.01	2.49	0.09*	<0.01	3.4**	<0.01
	Cotton	CA cotton	1.05	0.82	0.03	<0.01	1.1**	<0.01
	Potato	FL potato	2.64	2.30	0.08*	<0.01	3.1**	<0.01
	Potato	ID potato	0.72	0.64	0.02	<0.01	0.9	<0.01
	Cucurbit	FL cucumber	5.38	4.02	0.15*	<0.01	5.4**	<0.01
	Cucurbit/Lettuce	CA lettuce	2.95	2.58	0.08*	<0.01	3.5**	<0.01
Aerial	Tree fruit	Orchard	4.80	4.14	0.14*	<0.01	5.6**	<0.01
	Tree fruit/almonds	CA almond	0.89	0.73	0.03	<0.01	1.0	<0.01
	Nursery	CA nursery	2.00	1.73	0.06*	<0.01	2.3**	<0.01
	Forestry	OR Christmas tree	3.06	2.78	0.09*	<0.01	3.8**	<0.01
	Forestry	NC apple	5.82	5.02	0.17*	<0.01	6.8**	<0.01
	Cotton	MS cotton	2.85	2.29	0.08*	<0.01	3.1**	<0.01
	Cotton	CA cotton	0.66	0.52	0.02	<0.01	0.7	<0.01
	Potato	FL potato	2.43	2.11	0.07*	<0.01	2.9**	<0.01
	Potato	ID potato	0.41	0.36	0.01	<0.01	0.5	<0.01
	Cucurbit	FL cucumber	5.03	3.76	0.14*	<0.01	5.1**	<0.01
	Cucurbit/Lettuce	CA lettuce	2.48	2.19	0.07*	<0.01	3.0**	<0.01
	Cranberry	OR berry	0.52	0.45	0.01	<0.01	0.6	<0.01
Ground	Tree fruit	BSS Orchard	4.45	3.85	0.13*	<0.01	5.2**	<0.01
	Tree fruit/almonds	CA almond	0.49	0.42	0.01	<0.01	0.6	<0.01
	Nursery	TN nursery	2.77	2.16	0.08*	<0.01	2.9**	<0.01
	Nursery	CA nursery	1.10	0.95	0.03	<0.01	1.3**	<0.01
	Turf	FL turf	1.44	1.14	0.04	<0.01	1.5**	<0.01
	Turf	CAT turf	3.80	3.39	0.11*	<0.01	4.6**	<0.01
	Forestry	OR Christmas tree	2.19	1.99	0.06*	<0.01	2.7**	<0.01

		,			r			r	
			- 40			-0.01		1 001	
	Lorestry	NC apple	5.13	4.47	0.15*	<0.01	6.0**	(0.01)	
	10,000,		0.10		0	.0.01	0.0		

^{*}Value exceeds listed species LOC (0.05).

Table 42. Soil treatments: Summary of Acute and Chronic RQs for Freshwater (FW) and saltwater (SW) Invertebrates

		EEC	(μg a.i./L)				RQ
Use	Scenario	1-day	21-day	FW Invert Acute ¹	SW invert acute ²	FW Invert	SW Invert chronic ⁴
Citrus	FL citrus	3.22	2.70	0.09*	<0.01	3.6**	<0.01
Cucurbit	FL cucumber	3.94	2.95	0.11*	<0.01	4.0**	<0.01
Cucurbit/Lettuce	CA lettuce	3.79	3.34	0.11*	<0.01	4.5**	<0.01
Radish/carrot	FL carrot	2.28	1.91	0.07*	<0.01	2.6**	<0.01
Radish/onion	CA onion	0.35	0.31	0.01	<0.01	0.4	<0.01
Grape	NY grape	2.08	1.71	0.06*	<0.01	2.3**	<0.01
Grape	CA grape	0.94	0.82	0.03	<0.01	1.1**	<0.01
Cranberry	OR berry	0.74	0.65	0.02	<0.01	0.9	<0.01
Nursery	TN nursery	2.72	2.17	0.08*	<0.01	2.9**	<0.01
Nursery	CA nursery	1.05	0.91	0.03	<0.01	1.2**	<0.01
Turf	FL turf	1.17	0.91	0.03	<0.01	1.2**	<0.01
Turf	CA turf	3.08	2.75	0.09*	<0.01	3.7**	<0.01
	OR Christmas				<0.01		<0.01
Forestry	tree	1.98	1.77	0.06*		2.4**	
Forestry	NC apple	3.65	3.13	0.10*	<0.01	4.2**	<0.01

^{*}Value exceeds listed species LOC (0.05).

Table 43. Seed Treatments: Summary of Acute and Chronic RQs for Freshwater (FW) and saltwater (SW) Invertebrates

		EEC (μ	g a.i./L)	RQ				
Use	Scenario	1-day	21-day	FW Invert Acute ¹	SW invert acute ²	FW Invert chronic ³	SW Invert chronic ⁴	
Cotton	MS cotton	0.51	0.42	0.01	<0.01	0.6	<0.01	
Cotton	CA cotton	0.08	0.07	<0.01	<0.01	0.1	<0.01	
Corn	MS corn	0.00	0.00	0.00	0.00	0.0	0.00	
Corn	CA corn	0.00	0.00	0.00	0.00	0.0	0.00	
Soybean	MS soybean	0.03	0.02	<0.01	<0.01	0.0	<0.01	

^{**}Value exceeds chronic LOC (1.0).

 $^{^{1}}$ Calculated using 1-d EEC and 48-h EC₅₀ = 35 µg a.i./L (MRID 44714918).

 $^{^{2}}$ Calculated using 1-d EEC and 96-h LC₅₀ = 6900 µg a.i./L (MRID 44714922).

 $^{^{3}}$ Calculated using 21-d EEC and NOAEC = 0.74 μ g a.i./L (Cavallaro et al. 2016).

 $^{^{4}}$ Calculated using 21-d EEC and NOAEC = 1100 μ g a.i./L (MRID 49589510).

^{**}Value exceeds chronic LOC (1.0).

 $^{^{1}}$ Calculated using 1-d EEC and 48-h EC₅₀ = 35 µg a.i./L (MRID 44714918).

 $^{^{2}}$ Calculated using 1-d EEC and 96-h LC₅₀ = 6900 μ g a.i./L (MRID 44714922).

 $^{^3}$ Calculated using 21-d EEC and NOAEC = 0.74 μ g a.i./L (Cavallaro et al. 2016).

 $^{^4}$ Calculated using 21-d EEC and NOAEC = 1100 μ g a.i./L (MRID 49589510).

Soybean/corn	CA corn	0.01	0.01	<0.01	<0.01	0.0	<0.01
Cusanhaat	MN sugar				< 0.01		< 0.01
Sugar beet	beet	0.27	0.25	0.01		0.3	
Cugarbaat	CA sugar				< 0.01		< 0.01
Sugar beet	beet	0.54	0.50	0.02		0.7	
Wheat	TX wheat	0.00	0.00	0.00	0.00	0.0	0.00
Wheat	CA wheat	0.00	0.00	0.00	0.00	0.0	0.00
Rice	MS rice	4.13***	3.81***	0.12*	<0.01	5.1**	<0.01
Rice	CA rice	66.4***	35.5***	1.90+	0.01	48**	0.03

^{*}Value exceeds listed species LOC (0.05).

4.1.4. Risk to Birds and Mammals

In the following sections, RQ values are calculated for terrestrial organisms (**Tables 44-**) based on the exposure estimates in **Section 2.4.1** and toxicity values outlined in **Section 3.2**. Risks are estimated based on an upper-bound of application rate for both foliar agricultural (0.086 lb a.i./A) and soil agricultural/non-agricultural uses (0.265). This use rate is also considered protective of the seed treatment uses as the amount of a.i. per unit area approaches the maximum amount allowed for seed treatments. In general, there are few exceedances of the LOC for all scenarios. The results are presented below with additional characterization where necessary.

4.1.4.1. Risk to Birds

Foliar and Soil Applications

Tables 44 and 45 show both acute dose-based and chronic dietary based risk quotients for thiamethoxam applied 1, 2, or 3 times the maximum foliar rate (0.086 lb a.i./A) and a single application to soil (inclusive of dietary residues resulting from turf and non-agricultural Christmas tree applications at 0.265 lb a.i./A). Ranges are provided to simplify rows where all feeding categories were below both the listed and non-listed LOCs. As shown by the table, the acute listed (0.1) LOC was mostly exceeded for herbivorous small bids at the higher application rates (2 or 3 apps at 0.086 lb a.i./A or 1 app at 0.265 lb a.i./A). RQs were also at the listed LOC of 0.1 for small insectivorous birds and medium herbivorous birds at 1 application of 0.256 lb a.i./A.

Table 44. Avian acute dose-based¹ and chronic dietary-based² RQs based on maximum single application rate of 0.086 lb a.i./A

Facilities Cake and	Acute dose-based RQs										
Feeding Category	Small (20 g)			Medium (100	Large (1000 g)						
	1 app	2 apps	3 apps	1 app 2 apps	3 apps	1 app	2 apps	3 apps			
Short Grass		0.15*	0.21*	All RQs <0.01-0.09							
Tall Grass			0.09								

⁺Value exceeds non-listed (0.5) and listed species (0.05) LOCs.

^{**}Value exceeds chronic LOC (1.0).

^{***}EEC generated using PFAM

 $^{^{1}}$ Calculated using 1-d EEC and 48-h EC₅₀ = 35 μ g a.i./L (MRID 44714918).

 $^{^{2}}$ Calculated using 1-d EEC and 96-h LC₅₀ = 6900 μ g a.i./L (MRID 44714922).

 $^{^3}$ Calculated using 21-d EEC and NOAEC = 0.74 μ g a.i./L (Cavallaro et al. 2016).

 $^{^4}$ Calculated using 21-d EEC and NOAEC = 1100 μ g a.i./L (MRID 49589510).

Broadleaf plants	ALLDO	AU DOs	0.12*						
Fruits/pods	All RQs <0.01-	All RQs	All RQs						
Arthropods	0.01-	<0.01- 0.08	<0.01-						
Seeds	0.08	0.06	0.08						
			Ch	ronic Dietary Based RQs (mg/kg-diet)					
Short Grass									
Tall Grass									
Broadleaf plants				All RQs <0.01-0.18					
Fruits/pods				All NQS <0.01-0.16					
Arthropods	Arthropods								
Seeds									

¹ Mallard duck LD₅₀ of 576 mg/kg-bw (MRID 44703307)

Table 45. Avian acute dose-based¹ and chronic dietary-based² RQs based on maximum single application rate of 0.265 lb a.i./A

Fandling Cakenana	Acu	ite dose-based RQs (mg/kg-bw)	
Feeding Category	Small (20 g)	Medium (100 g)	Large (1000 g)
Short Grass	0.2*	0.1*	
Tall Grass	0.1*	0.05	
Broadleaf plants	0.1*	0.1*	All DO: 40.01
Fruits/pods	0.02		All RQs ≤0.01
Arthropods	0.1* All RQs <0.01-0.04		
Seeds	<0.01		
	Chron	ic Dietary Based RQs (mg/kg-diet)	
Short Grass			
Tall Grass			
Broadleaf plants		All DO - <0.03	
Fruits/pods		All RQs ≤0.02	
Arthropods			
Seeds			

¹ Mallard duck LD₅₀ of 576 mg/kg-bw (MRID 44703307)

Treatment directly to soil (rows, in-furrow, band) is an additional potential route of exposure for birds via dietary items. The $LD_{50}/ft^{2.22}$ analysis is used to estimate risk for this type of application (in addition to granular applications). As a conservative screen, a broadcast application rates 0.265 to soil with no incorporation were modeled and yielded an estimated 2.76 mg a.i./ft². This is considered conservative because it is the highest amount of a.i. with no modeled incorporation or covering leaving the entire treated area as a potential route of exposure. The results showed a potential risk concern for listed (LOC of 0.1 exceeded) small birds (**Table 46**). Additionally, as noted in **Section 2.4.1** EFED compared the upper bound Kenaga EECs in arthropods following foliar applications as a surrogate for potential exposures of likely dietary items following soil exposures. Based on this analysis, there are no LOC exceedances for birds consuming arthropods. However, based on the conservative assumptions of the

² Mallard duck NOAEL 61 mg/kg-bw per day (MRID 44718707)

^{*}At or exceeds the listed species LOC (0.1)

² Mallard duck NOAEL 61 mg/kg-bw per day (MRID 44718707)

^{*}At or exceeds the acute listed species LOC (0.1)

²² The LD₅₀/ft² is only used to estimate risk from acute exposures.

 LD_{50}/ft^2 analysis there are potential risk issues for listed small birds from soil treatments at these application rates.

Table 46. Avian acute and chronic RQs for soil applications at 0.265 lb a.i./A based on LD⁵⁰/ft² and dietary analysis

Size Class	LD ₅₀ /ft ²		Acute - Arthropod		Chronic - Arthropod	
	EEC	RQ	EEC - Dose	RQ	EEC - Dietary	RQ
Small (20 g)	2.76 ¹	0.46	28.4	0.09	25	0.1
Medium (100 g)		0.07	16.2	0.04		
Large (1000 g)		0.01	7.2	0.01		

¹ mg a.i./ft² and based on broadcast spray with no incorporation.

Bold values exceed the acute listed (0.1) LOC.

Seed Treatments

For assessing acute risk related to treated seeds, a dose-based RQ 23 is calculated, where the exposure metric is an estimated ingested dose (mg a.i./kg-bw) based on the pesticide concentration on the treated seed and the allometric food ingestion rate 24 . An area-based RQ 25 , analogous to an LD $_{50}$ ft 2 is also calculated based on the mass of active ingredient per unit area (square foot). This method simply compares the amount pesticide expected to be present in a square foot to the acute LD $_{50}$ and does not include any specific estimation of pesticide ingested doses. Chronic risks are estimated using a "diet based" approach by comparing the concentration of pesticide on the treated seed divided by the chronic diet-based NOAEC.

Table 47 below shows the calculated RQs for birds for several different crop commodities sewn with treated seed. As previously mentioned these were chosen based on high acreage planted (e.g. corn, soybean, cotton) and to provide a range of application rates (e.g. cotton 0.071 lb a.i./A to sugar beet 0.167 lb a.i./A), use consideration, and seed size. Depending on the size of the bird, there are acute non-listed exceedances for all crops except soybean, acute listed exceedances for all crops (mainly for small birds), and chronic exceedances for all modeled crops and size classes.

Table 47. Acute Dose based, mg a.i./ft2 based and Chronic¹ exposure based RQs for birds from exposure to thiamethoxam treated seed.

Crop	Exposure	Small (20g)	Med (100g)	Large (1000g)	
Sugar Beet	Dose Based	29.6*	13.3*	4.2*	
	LD ₅₀ /ft ²	0.29	0.05	<0.01	
	Chronic	117			
Corn	Dose Based	3.26*	1.46*	0.46	
	LD ₅₀ /ft ²	0.20	0.03	<0.01	
	Chronic	12.8			
Soy	Dose Based	0.42	0.19	0.06	
	LD ₅₀ /ft ²	0.15	0.02	<0.01	

 $^{^{23}}$ RQ = [(Seed Application Rate (mg a.i./kg-seed) * daily food intake (g/day) * 0.001 kg/g) / body weight of animal (kg)] / Adjusted (bw) Toxicity Endpoint (LD50)

²⁴ Assumes 100% of the diet is composed of treated seeds and does not presently account for the probability of consuming a treated seed which may be reduced with soil incorporation of seeds.

²⁵ RQ = [(Application Rate (lbs a.i./A) * 1,000,000 mg/kg) / (43,560 ft2 * 2.2 lb/kg)] / Adjusted LD50)

Crop	Exposure	Small (20g)	Med (100g)	Large (1000g)
	Chronic		1.7	
Cotton	Dose Based	3.19*	1.43*	0.45
	LD ₅₀ /ft ²	0.12	0.02	<0.01
	Chronic		12.6	

¹ Chronic RQ values are the same for all size classes.

4.1.4.2. Risks to Mammals

Foliar and Soil Applications

There were no LOC exceedances (**Tables 48, 49, and 50**) for mammals from any application rate (0.086 lb a.i./A, 0.265 lb a.i/A), application number (1, 2, 3)²⁶, or type (for foliar or soil applications). Unlike birds, the LD₅₀/ft² analysis did not yield any concerns for foraging mammals. Additionally, considering arthropod RQs did not exceed the LOC, so no further characterization was done.

Table 48. Mammalian dose-based acute and chronic RQs based on maximum single application rate of 0.086 lb a.i./A

1000 10 4111/11								
Feeding Category			Acute	e dose-bas	ed RQs			
recuing Category		Small (15 g)	Me	edium (35	g)	Large (1000 g)		
	1 app	2 apps 3 apps	1 app	2 apps	3 apps	1 app	2 apps	3 apps
Short Grass								
Tall Grass								
Broadleaf plants				All DOs ZO	01			
Fruits/pods		All RQs ≤0.01						
Arthropods								
Seeds								
			Chron	ic dose-ba	sed RQs			
Short Grass				0.07-0.39	9			
Tall Grass				0.03-0.18	 3			
Broadleaf plants				0.04-0.22	2			
Fruits/pods				<0.01-0.0	2			
Arthropods				0.03-0.15	5			
Seeds			All R	Qs All RQs	≤0.01			

Table 49. Mammalian dose-based RQs based on single application rate of 0.256 lb a.i./A

Familian Cakanani	Acute dose-based RQs (mg/kg-bw)							
Feeding Category	Small (15 g)	Medium (35 g)	Large (1000 g)					
Short Grass								
Tall Grass								
Broadleaf plants		All DO0.01.0.03						
Fruits/pods		All RQs <0.01-0.02						
Arthropods								
Seeds								

²⁶ 2 or 3 applications for foliar rate of 0.086 lb a.i./A only.

^{*} Exceeds the non-listed LOC (0.5) and listed LOC (0.1); *Italicized* text exceeds the listed LOC (0.1); **Bold** text exceeds the chronic listed and non-listed LOC (1)

	Chronic dose-based RQs (mg/kg-bw)
Short Grass	0.21-0.45
Tall Grass	0.09-0.21
Broadleaf plants	0.12-0.25
Fruits/pods	0.01-0.03
Arthropods	0.08-0.18
Seeds	All RQs ≤0.01

Table 50. Mammalian acute and chronic RQs for soil applications at 0.265 lb a.i./A based on LD⁵⁰/ft² and dietary analysis

Size Class	LD ₅	o/ft²	Acute - Arthropod		Chronic - Arthropod	
	EEC	RQ	EEC – Dose	RQ	EEC - Dietary	RQ
Small (15 g)		0.05	23.7	≤0.01		
Medium (35 g)	2.76 ¹	0.03	16.4		25	0.02
Large (1000 g)	1	<0.01	3.8			

¹ mg a.i./ft² and based on broadcast spray with no incorporation.

Seed treatments

Acute RQs from seed treatment uses are calculated for mammals in the same manner as birds (**Section 4.1.4.1** – **Seed treatments**). For mammals (unlike birds), chronic RQs are calculated using a "dose-based" approach whereby the ingested dose of pesticide is divided by the dose-based NOAEL. The non-listed acute LOC was exceeded (**Table 51**) for seed treatment uses on sugar beet only while the acute listed LOC was exceeded for corn and cotton. The chronic LOC was exceeded for corn, cotton, and sugar beet. There were no LOC exceedances for soybean.

Table 51. Acute Dose based, mg a.i./ft² based and Chronic exposure based RQs for Mammals from exposure to thiamethoxam treated seed.

Crop	Exposure	Small (15g)	Med (35g)	Large (1000g)
Sugar Beet	Dose Based	2.16*	1.84*	0.99*
•	LD50/ft2	0.03	0.02	0.00
	Chronic	55.33	47.26	25.33
Corn	Dose Based	0.24	0.20	0.11
	LD50/ft2	0.08	0.10	0.00
	Chronic	6.08	5.20	2.79
	Dose Based	0.03	0.03	0.01
Soy	LD50/ft2	0.02	0.01	0.00
	Chronic	0.79	0.68	0.36
Cotton	Dose Based	0.23	0.20	0.11
	LD50/ft2	0.01	0.01	0.00
	Chronic	5.97	5.10	2.73

^{*} Exceeds the non-listed LOC (0.5) and listed LOC (0.1); *Italicized* text exceeds the listed LOC (0.1); **Bold** text exceeds the chronic listed and non-listed LOC (1)

4.1.4.3. Risks to Terrestrial Plants

RQs for terrestrial plants are presented below in **Table 52.** These are based on the single highest rate: 1 ground application at 0.265 lb a.i./A. RQs. Based on the reviewed data there are exceedances for non-listed dicots in semi-aquatic habitats. RQs for non-listed monocots could not be calculated due to non-definitive values which were greater than the maximum application rate in both the vegetative vigor and seedling emergence studies. RQs were not calculated for non-listed monocots due to non-definitive IC₂₅ values in both the seedling emergence and vegetative vigor tests. At the maximum application rate tested (0.28 lb a.i./A), the highest % effect seen was in onion weight at 23% in the seedling emergence test, and in the vegetative vigor test 11.1% effect on sugar beet height. RQs were not calculated for listed dicots because there were statistically significant reductions in height at the lowest treatment level (0.017 lb a.i./A) resulting in a non-definitive NOAEC. It was determined the IC₀₅ could not be used in lieu of the NOAEC due to unbounded 95% confidence interval.

Table 52. Risk Quotients for terrestrial plants in dry areas, semi-aquatic areas, and due to spray drift

Application Rate	Plant Type	Listed Status	Dry	Semi-Aquatic	Spray Drift
1 ground	Monocot	non-listed	NC	NC	NC
application@		Listed	<0.1	0.48	<0.1
0.265 lb a.i/A	Dicot	non-listed	0.57	4.83	<0.1
		listed	NC	NC	NC

Bold value exceeds the plant LOC (1)

4.2. Risk Description

In risk description, results from the risk estimation are interpreted and synthesized into overall risk conclusions. This description considers other lines of evidence (e.g., monitoring data, field data, incident reports, etc.) for characterizing ecological risk. In addition, the risk description also contains a discussion of relevant sources of uncertainty in the risk assessment and sensitivity of the risk assessment findings to important methodological assumptions. It also addresses other concerns including risks to threatened and endangered species.

4.2.1. Fish, Aquatic-Phase Amphibians and Aquatic Plants

LOCs were not exceeded for fish (surrogates for aquatic-phase amphibians) or aquatic plants. When compared to EECs, the toxicity values are orders of magnitude higher than the EECs. Therefore, potential risk to fish, aquatic-phase amphibians, and aquatic plants are considered low.

4.2.2. Aquatic Invertebrates

Based on RQs for freshwater invertebrates, there are risk concerns for acute exposures from some uses (rice seed treatment for non-listed species; several foliar and soil treatments for listed species) There are chronic risk concerns for the majority of foliar and soil treatment uses, as well as seed treatment of rice.

When considering the LOEC for chronic effects, EECs for several foliar and soil treatment uses and seed treatment on rice also exceed the LOEC. Exceptions include foliar and soil applications to nurseries, ground applications to potatoes, soil applications to radish, soil applications to grape. For these uses, there is uncertainty in the chronic risks as effects occur between the NOEC and LOEC. For those uses

where exposure exceeds the LOEC (e.g., foliar applications to cotton, foliar and soil applications to cucurbits), there is less uncertainty in the chronic risk conclusions.

RQs are based on 1-in-10 year frequencies. An analysis was conducted on the 30-year time series generated by PWC to evaluate how frequently daily values exceed toxicity endpoints (i.e., LOECs and NOECs) for aquatic invertebrates (**Table 53**). This analysis focuses on foliar thiamethoxam uses on cotton. These uses were selected because they are major uses of thiamethoxam, as identified in the SLUA and pose a risk (i.e., RQ>LOC). As summarized in **Table 53**, exposure estimates for foliar applications may exceed the NOEC 10-29 of the simulated years, with several exceedances of the LOEC (for the MS cotton scenario). In general, the number of exceedances in the CA scenarios are less than those in the MS scenarios. This can be attributed to more frequent rainfall events in MS. **Figures 1-3** depict the 21-d rolling water column concentrations for foliar treatments to cotton.

Table 53. Comparison of 30 years of daily water column concentrations to chronic endpoints (i.e., NOEC and LOEC) for aquatic invertebrates.

Application method	PWC scenario	Chronic RQ	# years where NOEC (0.74 ug/L) is exceeded	# years where LOAEC (2.23 ug/L) is exceeded
Foliar (aerial)	CA cotton	1.1	29	0
,	MS cotton	3.4	15	3
Foliar (ground)	CA cotton	0.7	0	0
,	MS cotton	3.1	10	3

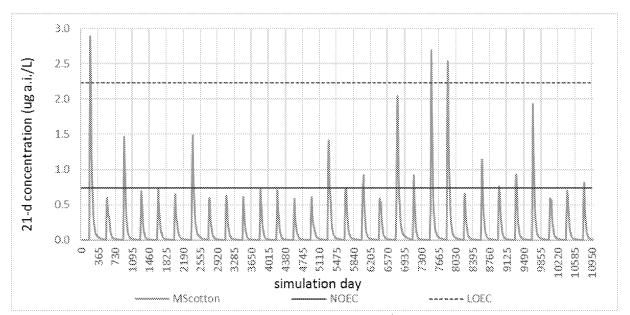


Figure 1. 21-d rolling EECs generated using <u>MScotton</u> scenario for <u>aerial</u> applications to cotton. Chronic invertebrate LOEC and NOEC included for reference.

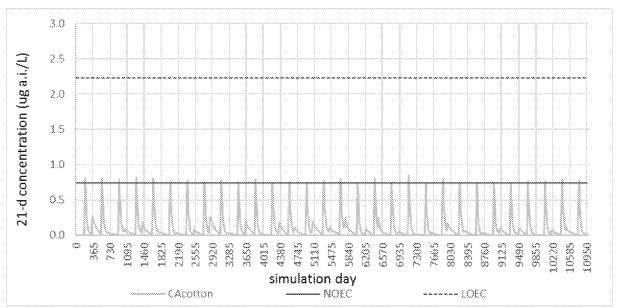


Figure 2. 21-d rolling EECs generated using <u>CAcotton</u> scenario for <u>aerial</u> applications to cotton. Chronic invertebrate LOEC and NOEC included for reference.

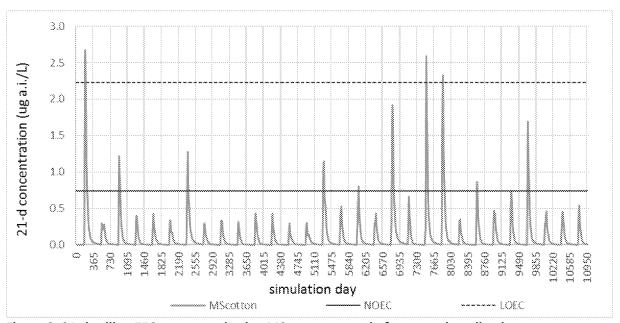


Figure 3. 21-d rolling EECs generated using <u>MScotton</u> scenario for <u>ground</u> applications to cotton. Chronic invertebrate LOEC and NOEC included for reference.

Incorporation depth has a significant impact on aquatic EECs, with deeper seeds resulting in lower EECs (for more on this the reader is referred to the analysis conducted in the imidacloprid ecological risk assessment [USEPA, 2017]). As a result, the aquatic EECs for seed treatment generated in this assessment may under- or over-estimate concentrations typically seen in waterbodies receiving runoff from fields with treated seeds.

When considering the available monitoring data, the highest detected sample was 4.37 μ g a.i./L (sample from CA collected in 2016). This value is within the same order of magnitude of 1-in-10 year 1-day EECs range 0.14-5.8 μ g a.i./L. The highest concentration detected in the monitoring data is above the NOEC (0.74 μ g a.i./L) and LOEC (2.23) for chronic effects to invertebrates.

There is some uncertainty associated with the chronic toxicity endpoint used in this assessment for aquatic invertebrates. Test organisms were exposed to thiamethoxam through the benthic layer (composed of sand and pore water); however, exposure was quantified in the overlaying water. It is assumed that pore water and overlaying water concentrations were equivalent because of the following:

- 1. Thiamethoxam has low Koc values (it is expected that pore water and overlying water will be very similar at equilibrium; this is supported by comparison of water column and pore water EECs generated by PWC that differ by a factor of 1.3-4.4)
- 2. There is a *de minimus* amount of organic carbon in the sand matrix, therefore, sorption of compounds to the organic of the benthic layer is not expected to be substantial.
- 3. The coarse particle size of the sand facilitates exchange between the overlying water and pore water, allowing for equilibrium to occur within a short period of time.

When considering toxicity data available for other aquatic invertebrates, those species that are not in the insect class are orders of magnitude less sensitive. Exposure estimates are below the toxicity endpoints, suggesting that non-insect aquatic invertebrates (e.g., cladocerans, bivalves) are less likely to be impacted by thiamethoxam exposures. Toxicity data used quantitatively in this assessment (i.e., to derive RQs) were based on midges (48-EC $_{50}$ = 35 ug a.i./L; 40-d NOAEC = 0.74 ug a.i./L). Qualitative data available for another species of insect (mayfly (Cloeon dipterum); 96-h EC $_{50}$ = 20 ug a.i./L; 28-d EC $_{10}$ = 0.13 ug a.i./L; Van Den Brink et al. 2016) show a similar level of sensitivity compared to midges.

One uncertainty associated with this assessment is that the stressor of concern is thiamethoxam only. Three of 14 aerobic soil metabolism studies reported the formation of clothianidin as a major degradate. As discussed previously, clothianidin is a neonicotinoid insecticide. Available toxicity data suggest that clothianidin may be more toxic to midges compared to thiamethoxam (e.g., Cavallaro et al. 2016). Thiamethoxam alone poses a risk to aquatic invertebrates for the majority of foliar and soil uses. Also, since clothianidin was only observed as a major degradate in 3 of 14 aerobic soil metabolism studies, it is not expected that the soil metabolism half-life parameter (which is based on the 90th percentile value) will be substantially impacted. Therefore, EECs are not expected to be impacted substantially. Another degradate NOA-404617, which maintains the N-nitro group, may also be of similar toxicity compared to thiamethoxam. This degradate was detected as a major degradate in one study (aerobic aquatic metabolism). If the aerobic aquatic metabolism half-life is assumed to be stable to account for this degradate, 1-d EECs would increase slightly (a factor of 1.0-2.8). Since no toxicity data are available for this degradate, it is unknown whether this compound is of similar toxicity to thiamethoxam. In summary, although clothianidin and NOA-404617 were not quantitatively incorporated into this assessment (i.e., through modeling a total residue approach to derive EECs), EECs for thiamethoxam alone are sufficient to pose a risk to aquatic invertebrates for all uses. Given that EECs for thiamethoxam alone are orders of magnitude below endpoints for other aquatic taxa (i.e., fish and aquatic plants), risk conclusions are expected to be influenced by exclusion of degradates from the EECs.

4.2.3. Birds

Foliar Applications

Acute, dose-based RQs were calculated for birds. When considering LOCs, these RQs suggest potential risk of mortality to listed species (no non-listed exceedances) from multiple applications of 0.086 lb a.i./A or the single highest application rate (0.265) for turf or ornamentals. Specifically, potential effects were identified for small and medium herbivorous birds and small insectivores. Acute listed LOC exceedances exist for the small birds consuming short grass (the highest RQs) for up to 45 days based on a 3 applications at 0.086 lb a.i./A or a single application at 0.256 lb a.i./A, suggesting foliar residues are present to cause mortality for a significant window after application. Given that most herbivorous species are expected to be classified large (USEPA 2015), it is less likely that herbivorous species will be at risk; however, smaller omnivorous species that consume available foliage (e.g., seedlings) may be at risk.

Acute dietary RQs were not calculated because the dietary LC_{50} study endpoints were all non-definitive (> 5200 mg a.i./kg-diet). This endpoint compared to the highest dietary EEC (64 mg a.i./kg-diet) is 2 orders of magnitude greater. Even comparing the NOAEC for sub-lethal effects 163 mg a.i./kg-diet is almost 3X this concentration.

The dose-based and diet-based toxicity testing approaches involve two different types of exposures and have inherent in them certain assumptions and uncertainties. The acute dose-based test is conducted with adult birds and assumes uptake and absorption kinetics of receiving a laboratory gavage dose (in which the chemical exposure is intense, and potentially highly bioavailable) could approximate the uptake and absorption from a dose in a dietary matrix. The acute dietary study is conducted with young chicks consuming food (that has potentially different nutrient content) at a rate also assumed to be similar to that in the field. Absorption and metabolism of a toxicant are likely variable across chemicals, organisms, and life stages. The oral dose test could represent a short-term exposure whereas the dietary exposure test could be representative of a more prolonged exposure period. Risk estimates suggest short-term intense exposures are more likely to result in mortality to listed bird species.

Risk quotients (and the number of days these RQs exceed the LOC noted above) are based on a default foliar dissipation half-life value of 35 days and the upper-bound Kenaga values on predicted in dietary items of birds, which represent a conservative estimate of thiamethoxam residues on plants. A shorter half-life would reduce potential exposure and the number of days LOC exceedances would occur leaving a shorter window for foliar residues to be at levels potentially causing mortality. Additionally, when mean Kenaga values, representing the average residues, along with the 35-day default half-life, are compared to the same toxicity data (**Table 54**), exposures are all well below levels that would represent an acute risk to birds (including listed and non-listed).

Table 54. Risk quotients generated using mean Kenaga residues for birds.

			Herbivores and Omnivores	res	Insectivore	Granivore		
Application Rate	Number of Apps	Size Class	Short Grass	Tall Grass	Broadleaf plants	Fruits/pods	Arthropods	Seeds
0.086 lb a.i./A	2	Constl	0.05	0.02	0.03	<0.01	0.04	<0.01
0.000 ID a.I./A	3	Small	0.07	0.03	0.04	0.01	0.06	<0.01
0.265 lb a.i./A	1	(20 g)	0.09	0.04	0.05	0.01	0.07	<0.01

Medium	0.04	0.00	0.03	-0.01	0.02	-0.01
(100 g)	0.04	0.02	0.02	<0.01	0.03	<0.01

When considering the available weight of evidence, although there are LOC exceedances, the risk of mortality to birds from acute exposures following foliar application appears low.

Soil Applications

The application rates of 0.086 and 0.256 lb a.i./A via broadcast spray were used as upper bounds contributing the most potential a.i./ft2 in any given foraging area for soil applications. According to the LD50/ft2 analysis, the assumption of a spray with 0 incorporation yielded listed LOC exceedances for small birds. The same analysis, assuming light incorporation (assumed 85%), would result in no LOC exceedances (RQ = 0.07) for small birds at 0.265 lb a.i./A (at a single application of 0.083 amount incorporated as low as 35% would keep RQs below the listed LOC). Many thiamethoxam soil uses are for band applications which are expected to be incorporated into the soil. Additionally, soil treatments (pre-plant) are expected to spray only sparse vegetation (less potential exposure) on the field rather than a dense patch of plant material. The dietary item subject to exposure in this scenario is insect s. The only RQ (0.1) was at the listed species LOC (also 0.1) for a single application at 0.256 lb a.i/A for arthropods. Considering incorporation is an expected practice and coupled with the likely sparse vegetative or insect dietary items lacking in a square foot of a soil treated field, lines of evidence suggest mortality resulting from thiamethoxam treated soil is unlikely.

Seed treatments

Seed treatments are the only use patterns with exceedances for both listed and non-listed bird species. There are several factors to consider when estimating risks to birds from seed treatment uses. Some of these factors include how much a.i. is on any given seed, how available that seed is (magnitude (#) and spatially (how close together available seeds are), and feeding biology of the foraging animal (e.g., can the bird physically handle/swallow the seed, the dietary requirements of a given bird species, and if the seed is palatable). Based on information from BEAD and EFED's Refinements for Risk Assessment of Pesticide Treated Seeds – Interim Guidance, **Table 49** provides an analysis to refine conclusions from RQ exceedances for birds. Considerations include how many seeds a bird would have to consume to reach the non-listed LOC, how much a granivorous bird eats in a day according to default T-REX assumptions, and size of the seed being consumed. This analysis assumes both availability and palatability of seed being 100%.

Acute Risks

The RQ analysis identified acute risk concerns for all size classes of non-listed birds consuming treated sugar beet seed and small/medium sized birds consuming treated corn and cotton seed. There were no non-listed exceedances for birds consuming soybean seed. According to EFED's Refinements for Risk Assessment of Pesticide Treated Seeds – Interim Guidance the species specific information on maximum seed size (mg) consumed by 20 g passerine birds (derived from Benkman and Pulliam 1988²⁷) is 60 mg

²⁷ Benkman, C.W. and H.R. Pulliam. 1988. Comparative Feeding Ecology of North American Sparrows and Finches. Ecology. 69: 1195—1199.

and for medium (100g) passerines is 120 mg. Based on an average weight of one field corn seed (270), and one cotton seed (101), these seeds are considered too big for most small passerine birds to consume. Field corn seeds are also considered too big for medium sized passerine birds to consume²⁸. According to USEPA 2015 there are 117 common species of birds associated with agricultural fields or their adjacent edge habitats and 89 of those species are passerines.

There is a noted uncertainty using size of seed as a limiting factor for consumption for all passerine species based on data from a few and using weight as the sole determination of seed size ²⁹; however, EFED considers this approach reasonable for foraging birds. Thus, acute and dietary risks from consumption of these seeds can be discounted for these size classes of passerines. Depending on the type of corn seed (e.g. sweet, pop, field, etc.) a size range of corn seeds exists such that the average seed size is below the weight threshold medium sized birds. Consequently, medium sized birds could be affected by consuming sweet corn or popcorn seeds. There were no non-listed LOC exceedances for birds consuming soybean seeds. **Table 56** shows the analysis and risk conclusions for non-listed bird species consuming treated seeds where the LOC was exceeded. This analysis includes the fraction of the diet represented by contaminated seeds that would constitute a risk to non-listed species.

Table 56. Number of seeds required to reach the LOC and % diet for bird size classes with LOC exceedances

Bird Size	Seed (weight in g)	Seeds to Reach LOC (0.5)	% Diet seeds to reach LOC (0.5) ¹	Potential Risks
Small (20g)	Field Corn	2	11%	Small and medium sized birds
Medium (100g)	(0.27 g)	15	29%	(excluding passerines)
Small (20g)	Cotton	8	16%	Small birds (excluding passerines)
Medium (100g)	(0.101g)	50	36%	and medium sized birds
Small (20g)		4	1%	
Medium (100g)	Sugar beet (0.014g)	26	3%	All size classes
Large (1000g)	(0.014g)	368	8%	

¹ Assuming 100% of diet is treated seed

This leaves non-listed LOC exceedances for all bird size classes potentially consuming smaller treated vegetable seeds (e.g. sugar beet), small (excluding passerines) and medium sized birds consuming cotton seeds, and small/medium birds (excluding passerines) consuming treated corn seeds. Additionally, any medium sized bird consuming popcorn or sweet corn seeds would also trigger a risk concern. The % of diet ranges from 1-36% required to reach the non-listed LOC. This analysis does not take into account seed availability due to incorporation, planting depth, availability, or palatability. Planted seeds were assumed available; however, the extent to which a bird will forage for planted seeds presumable covered by a layer of soil, or if seeds are uncovered, even how close these seeds may be spatially is an uncertainty. While 2 corn seeds are necessary to cause mortality for small birds, there is a difference if these seeds are 2 meters or an acre apart and the time commitment it would potentially take to find and consume these two seeds in the different scenarios.

²⁸ There were no non-listed exceedances for soybean; however, based on the average weight of one seed (178mg) this would be considered too large for small/medium passerine species.

²⁹ Differing chemical properties or coatings along with variation in the seed itself will alter the size of an individual seed.

There is also one incident reported that associated mortality of one robin and one flycatcher with corn planting. There is also uncertainty of the effects of this incident relatable directly to thiamethoxam as clothianidin was also used on the seed, and the plant based diets of these birds are more likely to be fruits. Although there is uncertainty in the, palatability, availability, and foraging effort to consume treated seeds, the low % of dietary requirement to consume these seeds suggest mortality is possible for birds from seed treatment uses, with higher concerns for those consuming smaller vegetable seeds.

Chronic risks to Birds

Chronic exceedances were also identified for all size classes and use patterns for both listed and non-listed species based on a NOAEC for the mallard duck at 300 mg/kg-bw. Effects seen were reduced body weight in parental males, with no other reproductive effects noted. The next dose (the LOAEC) was the highest tested (900 mg a.i./kg-bw). Comparisons of EECs to the LOAEC indicate that EECs are 4x higher for corn and cotton, and about 40x higher for sugar beet. Comparing results for soybean would suggest that the exposure is below the LOAEC.

There are several uncertainties related to chronic risks from seed treatments. It is not known if the effects seen (in this case weight loss in males) occur at a sensitive life stage or are due to the entire exposure period. This is particularly relevant when considering how many seeds an organism would have to consume to elicit the toxicological effect. Depending on the size of the bird as little as one seed per day could be consumed (if physically available) for the appropriate exposure period (either at the sensitive life stage, or a specific period of time) to produce toxicological effects.

Similar to analyses performed when considering acute exposures, corn, cotton, and soybean seeds are considered too big for small (20g) birds to consume while corn and soybean seeds are also considered too big for medium (100g) birds to consume based on EFED guidance. This leaves risk concerns for larger (1000g) birds and non-passerine smaller/medium birds. The number of seeds to reach the chronic NOAEC for all crops of these species ranged from 1-13 for corn, 2-110 for soybean, 1-43 for cotton and 1-23 for sugar beet. Considering this is a no effect level and there are doses between the NOAEC and LOAEC where exceedances start, the same seed number analysis was performed based on the LOAEC. The number of seeds to reach the chronic LOAEC for all crops of these species ranged from 1-39 for corn, 20-1793 for soybean, 3-130 for cotton and 1-68 for sugar beet.

How far apart and how many seeds are available are important factors to consider when discussing potential chronic risks. Seeds on the surface versus those incorporated and not as easily found by foraging birds reduce potential exposure and increase time required to find them decreasing the likelihood of potential chronic exposure. However, due to the low numbers of daily seed doses required to be at the NOAEL, risks from chronic exposure to treated seed cannot be discounted. The extent to which the effect seen in laboratory studies (decreased parental male size) is an uncertainty as to how this would ultimately translate to reproductive effects (i.e. decreased size could result in decreased mating success)

4.2.4. Mammals

Foliar and Soil applications

There were no LOC exceedances for mammals from any application rate (0.086 lb a.i./A, 0.265 lb a.i/A), application number (1, 2, 3) 30 , or type (for foliar or soil applications). Unlike birds, the LD $_{50}$ /ft 2 or arthropod dietary analysis did not yield any concerns for foraging mammals so no further characterization was done. Since RQs were all blow both the acute listed (0.1) acute non-listed (0.5) and chronic (1) LOC for foliar and soil applications there are no mortality or reproductive risk concerns for mammals.

Seed Treatments

The non-listed acute LOC (0.5) was exceeded for seed treatment uses on sugar beet only while the acute listed LOC (0.1) was exceeded for corn and cotton. There were no LOC exceedances for soybean. Unlike birds there is no size specific restriction for seed consumption considered. The number of seeds consumed required to reach the non-listed LOC ranges from 35-823 and would need to be 16-34% of the animal's diet consumed (depending on size). For mammals consuming corn and cotton seeds the number of seeds consumed required to reach the listed LOC (0.1) ranges from 14-313 (depending on size) and 4-95 for cotton and corn respectively. This ranges from 36-75% of a diet for corn seed consumers and 47-93% of diet for cotton seed consumers. These data suggest mortality is expected for listed seed eating mammals consuming treated seeds.

The chronic LOC was exceeded for corn, cotton, and sugar beet. There were no LOC exceedances for soybean. The reproductive effects seen in the chronic mammalian study were reduced body weight gain for offspring during the lactation period (NOAEL 61 mg/kg-bw/day; LOAEL 158 mg/kg-bw/day), with no other adverse, treatment-related effects (except some uncertain effects seen on tubular atrophy and sperm motility see effects **Section 3.2.2**) on reproductive parameters (mating, gestation, fertility, viability) noted at any dose level tested for the parents. The number of seeds required to reach the chronic LOC for corn, cotton, and sugar beet based on the NOEL ranges from 2-37, 5-123, and 3-64 respectively. While the range of seeds required to reach the chronic LOC for corn, cotton, and sugar beet based on the LOAEL is 4-96, 14-320, and 7-166 respectively. Newly planted fields, which are likely open and providing little cover for smaller foraging mammals may be less likely to pose a risk to seed eating mammals than those of the no till variety based on foraging behavior (assuming no cover = no forage). Additionally, similar to birds, actual chronic exposures from eating treated seeds per day is uncertain based on how many are available and how close they are. Despite these uncertainties, however, the low number of seeds required to reach even effects levels means reproductive effects to mammals cannot be discounted.

4.2.5. Terrestrial Plants

Risks are not expected for terrestrial monocots from runoff or spray drift. Although risk quotients were not calculated for non-listed species, RQs were below the LOC (1) based on a the NOAEC value for listed species. A definitive EC₂₅ value would not be less sensitive (lower) than the NOAEC for monocots and consequently any resulting RQs from a definitive endpoint would be higher than those based on the NOAEC. The RQ (4.8) exceedance for non-listed dicots in semi-aquatic habitats is based on the EC₂₅ value of 0.028 lb a.i/A. The reliability of this endpoint is considered highly uncertain. The confidence intervals in the regression for the IC₂₅ span an order of magnitude in the upper and lower bound (0.0025-0.23 lb a.i/A). With significant reductions in all test levels a NOAEC was not established < 0.017 lb a.i./A based on reduced cucumber height (weight reductions were not statistically significant and

³⁰ 2 or 3 applications for foliar rate of 0.086 lb a.i./A only.

ranged from 1.76% to 24.7% effects in the middle treatment doses). The IC $_{05}$ value calculated from the regression was not bounded by a lower CI and the upper CI was 7 orders of magnitude different than the estimate, indicating an unreliable regression model. Cucumber height effects ranted from 20.9% in the lowest (0.017 lb a.i./A) group to 32.9% in the highest (0.28 lb a.i./A) treatment group.

A new study with cucumber was submitted to the Agency (MRID 50131103) and is currently under review. The study authors reported no effects seen in cucumber at the highest application rate tested (0.265 lb a.i./A). This study used a different variety (Marketmore)³¹ of cucumber than the previous study (Spacemaster)³². It is possible effects seen in the original study are specific to the life stage of the specific variety of cucumbers as the effects seen in MRID 5013110 were in line with the other plant studies including no effects seen on cucumber in the vegetative vigor study (Spacemaster).

Considering study 50131103 (no effects) for cucumber would mean for seedling emergence all endpoints EC_{25} endpoints would be > the highest test concentration (0.265) with NOAEC values equal to or > the same concentration. It was also noted in the vegetative vigor study effects were seen in oilseed rape and onion at the lowest test concentration; however, the reviewer determined these effects were not treatment related and determined the EC_{25} and NOAEC values to be > and \geq the highest test concentration which would result in the following RQs (**Table 57**).

Table 57. RQs¹ for Terrestrial plants considering additional data.

Application Rate	Plant Type	Listed Status	Dry	Semi-Aquatic	Spray Drift
1 ground	Monocot	non-listed	NC	NC	NC
application @		Listed	<0.1	0.47	<0.1
0.265 lb a.i/A	Dicot	non-listed	NC	NC	NC
		listed	<0.1	0.49	<0.1

NC = Not calculated due to non-definitive endpoint (>)

There are not RQ exceedances for any listed species, and subsequently none would be expected for non-listed species. There are two incidents for corn (stand issues) and soybean (plant damage) reported. In both plant toxicity tests, corn and soybean had no effects reported and the plant injury scores were 0 for corn and only ranged from 0-9 for soybean, and although effects seen to cucumbers in one seedling emergence study cannot completely resolve uncertainty of potential risks to terrestrial dicots, the lines of evidence suggest risks to terrestrial plants are not expected (no effects greater than 25% in any other plants for survival, height, or weight).

4.3. Overall Conclusions

The primary risk concerns identified in this assessment involve acute and chronic exposures to freshwater aquatic insects as well as acute and chronic exposures to birds and mammals. For aquatic invertebrates, chronic risks are identified for all modeled foliar applications and soil applications (except

 $^{^{1}}$ Based on seedling emergence EC₂₅ and NOAEC values of >0.28/>0.265 and 0.28/0.265 respectively for monocots and dicots. Based on vegetative vigor EC₂₅ and NOAEC values of >0.28/0.28 for monocots and >0.28/0.061 for dicots

³¹ Supplied by Johnny's Selected Seeds, Windlow, Maine.

³² Supplied by Burpee, W. Atlee Burpee and Company, Burlington, North Carolina

cranberries) and seed treatment of rice. For birds and mammals, risks are focused around consuming treated seeds. No risk concerns were identified for fish or plants. There are no major gaps related to the environmental fate or toxicity databases. No acceptable data have been submitted to fulfill the requirement for acute oral toxicity data for a passerine species; however, sufficient avian toxicity data are available to complete the risk assessment.

5. Federally Threatened and Endangered (Listed) Species Concerns

Consistent with EPA's responsibility under the Endangered Species Act (ESA), the Agency will evaluate risks to listed species from registered uses of pesticides in accordance with the Joint Interim Approaches developed to implement the recommendations of the April 2013 National Academy of Sciences (NAS) report, Assessing Risks to Endangered and Threatened Species from Pesticides. The NAS report³³ outlines recommendations on specific scientific and technical issues related to the development of pesticide risk assessments that EPA and the Services must conduct in connection with their obligations under the ESA and FIFRA. EPA will address concerns specific to thiamethoxam in connection with the development of its final registration review decision for thiamethoxam.

In November 2013, EPA, the U.S. Fish and Wildlife Service, National Marine Fisheries (the Services), and USDA released a white paper containing a summary of their joint Interim Approaches for assessing risks to listed species from pesticides. These Interim Approaches were developed jointly by the agencies in response to the NAS recommendations, and reflect a common approach to risk assessment shared by the agencies as a way of addressing scientific differences between the EPA and the Services. Details of the joint Interim Approaches are contained in the November 1, 2013 white paper³⁴, Interim Approaches for National-Level Pesticide Endangered Species Act Assessments Based on the Recommendations of the National Academy of Sciences April 2013 Report.

Given that the agencies are continuing to develop and work toward implementation of the Interim Approaches to assess the potential risks of pesticides to listed species and their designated critical habitat, this ecological risk assessment supporting the registration review of thiamethoxam does not describe the specific ESA analysis, including effects determinations for specific listed species or designated critical habitat, to be conducted during registration review. While the agencies continue to develop a common method for ESA analysis, the risk assessment for the registration review of thiamethoxam describes only the level of ESA analysis completed at this time. This assessment allows EPA to focus its future evaluations on the types of species where the potential for effects exists, once the scientific methods being developed by the agencies have been fully vetted. Once the agencies have fully developed and implemented the scientific methods necessary to complete risk assessments for listed species and their designated critical habitats, these methods will be applied to subsequent analyses of thiamethoxam as part of completing this registration review.

6. Endocrine Disruptor Screening Program

As required by FIFRA and the Federal Food Drug and Cosmetic Act (FFDCA), EPA reviews numerous studies to assess potential adverse outcomes from exposure to chemicals. Collectively, these studies include acute, subchronic and chronic toxicity, including assessments of carcinogenicity, neurotoxicity, developmental, reproductive, and general or systemic toxicity. These studies include endpoints which

³³ http://www.nap.edu/catalog.php?record_id=18344

³⁴ http://www.epa.gov/espp/2013/nas.html

may be susceptible to endocrine influence, including effects on endocrine target organ histopathology, organ weights, estrus cyclicity, sexual maturation, fertility, pregnancy rates, reproductive loss, and sex ratios in offspring. For ecological hazard assessments, EPA evaluates acute tests and chronic studies that assess growth, developmental and reproductive effects in different taxonomic groups. As part of its registration review decision, EPA reviewed these data and selected the most sensitive endpoints for relevant risk assessment scenarios from the existing hazard database. However, as required by FFDCA section 408(p), thiamethoxam is subject to the endocrine screening part of the Endocrine Disruptor Screening Program (EDSP).

EPA has developed the EDSP to determine whether certain substances (including pesticide active and other ingredients) may have an effect in humans or wildlife similar to an effect produced by a "naturally occurring estrogen, or other such endocrine effects as the Administrator may designate." The EDSP employs a two-tiered approach to making the statutorily required determinations. Tier 1 consists of a battery of 11 screening assays to identify the potential of a chemical substance to interact with the estrogen, androgen, or thyroid (E, A, or T) hormonal systems. Chemicals that go through Tier 1 screening and are found to have the potential to interact with E, A, or T hormonal systems will proceed to the next stage of the EDSP where EPA will determine which, if any, of the Tier 2 tests are necessary based on the available data. Tier 2 testing is designed to identify any adverse endocrine-related effects caused by the substance, and establish a dose-response relationship between the dose and the E, A, or T effect.

Under FFDCA section 408(p), the Agency must screen all pesticide chemicals. Between October 2009 and February 2010, EPA issued test orders/data call-ins for the first group of 67 chemicals, which contains 58 pesticide active ingredients and 9 inert ingredients. A second list of chemicals identified for EDSP screening was published on June 14, 2013³⁵ and includes some pesticides scheduled for registration review and chemicals found in water. Neither of these lists should be construed as a list of known or likely endocrine disruptors. Thiamethoxam is not on List 1 or 2. For further information on the status of the EDSP, the policies and procedures, the lists of chemicals, future lists, the test guidelines and the Tier 1 screening battery, please visit our website.³⁶

7. References Cited

Ahmed, M. A. I. and F. Matsumura (2012). Synergistic Actions of Formamidine Insecticides on the Activity of Pyrethroids and Neonicotinoids Against Aedes aegypti (Diptera: Culicidae). J. Med. Entomol., AQUA, MIXTURE. 49: 1405-1410.

Barbee, G. C. and M. J. Stout (2009). Comparative Acute Toxicity of Neonicotinoid and Pyrethroid Insecticides to Non-Target Crayfish (Procambarus clarkii) Associated with Rice-Crayfish Crop Rotations. Pest Manag. Sci. gbarbee7@lsu.edu//, AQUA. 65: 1250-1256.

Cavallaro, M. C., Morrissey, C. A., Headley, J. V., Peru, K. M., & Liber, K. (2016). Comparative chronic toxicity of imidacloprid, clothianidin, and thiamethoxam to Chironomus dilutus and estimation of toxic equivalency factors. Environmental Toxicology & Chemistry, Accepted Article DOI: 10/1002/etc.3536

Food and Agriculture Organization of the United Nations (FAO). 2014. Assessing soil contamination.

86

³⁵ See https://www.regulations.gov/document?D=EPA-HQ-OPPT-2009-0477-0074 for the final second list of chemicals.

³⁶ http://www.epa.gov/endo/

reference manual; Parameters of pesticides that influence processes in the soil. Agriculture and Consumer Protection Department. http://www.fao.org/docrep/003/x2570e/x2570e06.htm

Hladik ML, Koplin DW. First national-scale reconnaissance of neonicotinoid insecticides in streams across the USA. Environ. Chem. 2016; 13: 12-20.

Huseth AS, Groves RL. Environmental fate of soil applied neonicotinoid insecticides in an irrigated potato agroecosystem. PLoS One. 2014; 9: e97081.

Main AR, Michel NL, Headley JV, Peru KM, Morrissey CA, et al. Ecological and Landscape Drivers of Neonicotinoid Insecticide Detections and Concentrations in Canada's Prairie Wetlands. Environ Sci Technol. 2015; 49: 8367-8376.

Main AR, Headley JV, Peru KM, Michel NL, Cessna AJ, Morrissey CA. 2014. Widespread use and frequent detection of neonicotinoid insecticides in wetlands of Canada's Prairie Pothole Region. PLoS ONE. 9:e92821. https://doi.org/10.1371/journal.pone.0092821 PMID: 24671127

Miles J.C., Hua J., Sepulveda M.S., Krupke, C.H., Hoverman, J.T. 2017. Effects of clothianidin on aquatic communities: Evaluating the impacts of lethal and sublethal exposure to neonicotinoids. PLoS ONE 12(3): e0174171. https://doi.org/10.1371/journal.pone.0174171

Mineau, P., Palmer, C. 2013. The Impact of the Nation's Most Widely Used Insecticides on Birds. American Bird Conservancy, March 2013.

Morrissey CA, Mineau P, Devries JH, Sanchez-Bayo F, Liess M, Cavallaro MC. 2015. Neonicotinoid contamination of global surface waters and associated risk to aquatic invertebrates: A review. Environ Int. 74:291±303. https://doi.org/10.1016/j.envint.2014.10.024 PMID: 25454246

Saraiva, A.S., R.A. Sarmento, A.C.M. Rodrigues, D. Campos, G. Federova, V. Zlabek, C. Gravato, J.L.T. Pestana and A.M.V.M. Soares. 2017. Assessment of thiamethoxam toxicity to Chironomus riparius. Ecotoxicol. and Environ. Safety. 137: 240-246.

Schaafsma A, Limay-Rios V, Baute T, Smith J, Xue Y, et al. Neonicotinoid insecticide residues in surface water and soil associated with commercial maize (corn) fields in southwestern Ontario. PLoS One. 2015; 10: e0118139

Tuttle G. 2014. Surface Water Monitoring Program for Pesticides in Salmonid-Bearing Streams, 2013 Data Summary. Data summary: a cooperative study by the Washington State Departments of Ecology and Agriculture. AGR PUB 103-411 (N/8/14)

Ugurlu, P., et al. (2015). The Toxicological Effects of Thiamethoxam on Gammarus kischineffensis (Schellenberg 1937) (Crustacea: Amphipoda). Environ. Toxicol. Pharmacol., AQUA. 39: 720-726.

Uragayala, S., et al. (2015). Adulticidal & Larvicidal Efficacy of Three Neonicotinoids Against Insecticide Susceptible & Resistant Mosquito Strains. Indian J. Med. Res., AQUA, TOP. 142: 64-70.

USEPA. 1999. Thiamethoxam: Results of the Health Effects Division's (HED) Metabolism Assessment Review Committee meeting (DP 258614). U.S. Environmental Protection Agency, Office of Prevention, Pesticides and Toxic Substances, Office of Pesticide

Programs, Washington DC.

USEPA. 1998. Guidelines for Ecological Risk Assessment. Published on May 14, 1998, Federal Register 63(93): 26846 – 26924. http://www.epa.gov/raf/publications/pdfs/ECOTXTBX.PDF

USEPA. 2011a. Registration Review: Problem Formulation for the Environmental Fate, Ecological Risk, Endangered Species, and Drinking Water Exposure Assessments for Thiamethoxam. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, December 13, 2011.

USEPA. 2011b. Thiamethoxam Summary Document Registration Review: Initial Docket December 2011. Environmental Protection Agency, Office of Pesticide Programs, Pesticide Re-evaluation Division and Antimicrobials Division, December 20, 2011.

USEPA, 2011c. Acres Planted per Day and Seeding Rates of Crops Grown in the United Sates. Biological and Economic Analysis Division (BEAD), Office of Pesticide Programs, United States Environmental Protection Agency.

USEPA. 2012. Thiamethoxam Final Work Plan Registration Review. Environmental Protection Agency, Office of Pesticide Programs, Pesticide Re-evaluation Division and Antimicrobials Division, June 2012.

USEPA. 2013. Generic Data Call-In Notice for Thiamethoxam (GDCI-060109-1309). Environmental Protection Agency, Office of Pesticide Programs, Pesticide Re-evaluation Division, March 18, 2013.

USEPA, 2013b. Guidance on modeling off-site deposition of pesticides via spray drift for ecological and drinking water assessments. Environmental Fate and Effects Division, Office of Chemical Safety and Pollution Prevention. U. S. Environmental Protection Agency.

USEPA. 2015. G Technical description and user's guidance document for the terrestrial investigation model (TIM). Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, March 25, 2015.

USEPA. 2016. Guidance for Selecting Input Parameters for the Pesticide in Flooded Applications Model (PFAM) Including Specific Instructions for Modeling Pesticide Concentrations in Rice Growing Areas, Version 1.0, PFAM Version 2.0. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, September 27, 2016.

USEPA. 2017a. Preliminary Bee Risk Assessment to Support the Registration Review of Clothianidin and Thiamethoxam. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division, January 5, 2017.

USEPA. 2017b. Preliminary Aquatic and Non-Pollinator Terrestrial Risk Assessment to Support the Registration Review of Clothianidin. Environmental Protection Agency, Office of Pesticide Programs, Environmental Fate and Effects Division.

Van Den Brink, P. J., et al. (2016). Acute and Chronic Toxicity of Neonicotinoids to Nymphs of a Mayfly Species and Some Notes on Seasonal Differences. Environ. Toxicol. Chem., AQUA. 35: 128-133 (Supplemental Journal Materials).

Appendix A. Degradates formed in Environmental Fate Studies with Thiamethoxam

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Maximum %AR (day)	Final %AR (study length)	
		PARENT	d				
Thiamethoxam	IUPAC: (EZ)-3-(2-chloro-1,3-thiazol-5-						
(CGA293343)	ylmethyl)-5-methyl-1,3,5-oxadiazinan- 4-ylidene(nitro)amine						
	CAS: 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-N-nitro-4H-1,3,5-oxadiazin-4-imine CAS No.: 153719-23-4 Formula: C ₈ H ₁₀ ClN ₅ O ₃ S MW: 291.71 g/mol SMILES: CN1COCN(C1=N[N+](=O)[O-])Cc2cnc(s2)Cl	H ₃ C N C S		PARENT			
	MAJO	R (>10%) AND MINOR TRANSFORMA	TION PRODUC	CTS			
CGA 322704	IUPAC: N -[(2-chloro-1,3-thiazol-5-	•		44703418	23.7% (365 d)	23.7% (365 d)	
(Clothianidin)	yl)methyl]-N'-methyl-N''-nitroguanidine			49589503	29.4% (220 d)	29.4% (220 d)	
,		н	Aerobic Soil	49589504	7.74% (120 d)	7.74% (120 d)	
	CAS: Guanidine, N -[(2-chloro-5-thiazolyl)methyl]-N'-methyl-N''-nitro-	N	Metabolism	49589505	3.4% (118 d)	3.4% (118 d)	
	thiazoryt/methylj-iv -methyl-iv -mto-	н _ /		49589506	18.9% (121 d)	18.9% (121 d)	
	CAS No.: 131748-59-9	N —		49589507	36.8% (90 d)	15.1% (363 d)	
	Formula: C ₆ H ₈ ClN ₅ O ₂ S MW: 249.67 g/mol	CI S N	Anaerobic soil	49829901	7.2% (90 d)	3.1% (153 d)	
	SMILES: CN/C(=N/[N+](=O)[O-])/NCc1cnc(s1)Cl	N	metabolism	49829902	17.3% (30 d)	10.1% (120 d)	

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Maximum %AR (day)	Final %AR (study length)
CGA 353042	CAS: 2H-1,3,5-Oxadiazine-4-amine, 3,6-dihydro-3-methyl	H ₃ C NH	Aqueous Photolysis	44715024	60.7 (30 d)	60.7 (30 d)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Maximum %AR (day)	Final %AR (study length)
NOA 407475 (CSAA468313)	IUPAC: 3-(2-Chloro-thiazol-5-ylmethyl)-5-methyl-[1,3,5]oxadiazinan-4-ylideneamine	N H	Anaerobic soil metabolism	49829901	14.2% (153 d)	14.2% (153 d)
	CAS: 4H-1,3,5-Oxadiazin-4-imine, 3- [(2-chloro-5- thiazolyl)methyl]tetrahydro-5-methyl-			49829902	13.5% (120 d)	13.5% (120 d)
				44715032	52.0% (30 d)	29.8% (365 d)
	Formula: C ₈ H ₁₁ ClN ₄ OS MW: 246.72 g/mol SMILES: CN1COCN(C1=N)Cc2cnc(s2)Cl		Aerobic Aquatic Metabolism	49589509	21.8% (70 d)	6.99% (100 d)
			Anaerobic	44715031	69.1 (271 d)	63.0 (365 d)
			Aquatic Metabolism	49589508	17.6 (70 d)	15.6 (100 d)
CGA 355190	IUPAC: 3-(2-Chloro-thiazol-5-		Hydrolysis	44703417	59.5% (30 d)	59.5% (30 d)
	ylmethyl)-5-methyl-[1,3,5]oxadiazinan- 4-one		Aerobic Soil Metabolism	44703418	23.7 (365 d)	23.7 (365 d)
	CAS: 4H-1,3,5-Oxadiazin-4-one, 3-[(2-chloro-5-thiazolyl)methyl]tetrahydro-5-methyl-		Anaerobic soil	49829901	14.0% (90 d)	6.0% (153 d)
	Formula: C ₈ H ₁₀ ClN ₃ O ₂ S MW: 247.7 g/mol		metabolism	49829902	31.0 % (120 d)	31.0% (120 d)
	SMILES: CN1COCN(C1=O)Cc2cnc(s2)Cl		Aerobic Aquatic	44715032	78.9% (115 d)	46.6% (365 d)
			Metabolism	49589509	6.92% (48 d)	3.04% (100 d)
			Anaerobic	44715031	24.4 (180 d)	19.0 (365 d)
			Aquatic Metabolism	49589508	31.3 (48 d)	21.7 (100 d)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Maximum %AR (day)	Final %AR (study length)
Carbon dioxide	IUPAC: Carbon dioxide			49589503	38.2 % (220 d)	38.2% (220 d)
				49589504	7.76% (120 d)	7.76% (120 d)
	Formula: CO ₂		Aerobic Soil Metabolism	49589505	4.20% (118 d)	4.20% (118 d)
	MW: 44 g/mol SMILES: C(=O)=O		Metabolism	49589506	21.1% (181 d)	21.1% (181 d)
	3141125. C(-0)-0			49589507	44.2% (363 d)	44.2% (363 d)
		o <u> </u>	Anaerobic soil metabolism	49829902	14.2% (120 d)	14.2% (120 d)
			Aerobic Aquatic	44715032	33.3 (365 d)	33.3 (365 d)
			Metabolism	49589509	12.0 (100 d)	12.0 (100 d)
			Anaerobic Aquatic Metabolism	49589508	2.58% (100 d)	2.58% (100 d)
Unextractable				49589503	12.1% (220 d)	12.1% (220 d)
Residues			Aerobic Soil Metabolism	49589504	10.9% (120 d)	10.9% (120 d)
				49589506	17.1% (181 d)	17.1% (181 d)
				49589507	21.4% (363 d)	21.4% (363 d)
			Anaerobic Soil	49829901	41.5% (153 d)	41.5% (153 d)
	NA	NA	Metabolism	49829902	20.9% (120 d)	20.9% (120 d)
			Aerobic Aquatic	44715032	38.6% (365 d)	38.6% (365 d)
			Metabolism	49589509	59.1% (70 d)	51.1% (100 d)
			Anaerobic Aquatic Metabolism	49589508	51.2% (70 d)	48.1% (100 d)

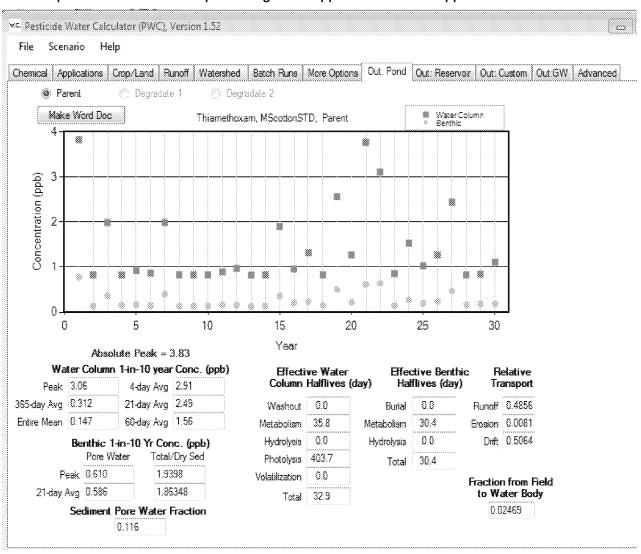
Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Maximum %AR (day)	Final %AR (study length)
CGA 309335	IUPAC: (2-Chlorothiazol-5-yl)- methylamine Formula: C ₄ H ₅ ClN ₂ S MW: 148.6 g/mol SMILES: [H]N([H])Cc1cnc(s1)Cl	CI S H	Hydrolysis	44703416	9.1% (30 d)	9.1% (30 d)
CGA 282149	IUPAC: 1-(2-Chlorothiazol-5-ylmethyl)- 3-methylurea		Soil Photolysis	44715028	3.17 (14 d)	0.75 (30 d)
	CAS No.: 153719-38-1 Formula: C ₆ H ₈ ClN ₃ OS MW: 205.6 g/mol SMILES: [H]N(C)C(=O)N([H])Cc1cnc(s1)Cl	S S S S S S S S S S S S S S S S S S S	Aerobic Soil Metabolism	44703418	6.80 (180 d)	2.75 (365 d)
NOA 404617	IUPAC: 1-(2-Chlorothiazol-5-ylmethyl)- 3-nitrourea		Anaerobic soil	49829901	6.6% (120 d)	0.8% (153 d)
	CAS: Urea, N-[(2-chloro-5-thiazolyl)methyl]-N'-nitro- Formula: C ₅ H ₅ ClN ₄ O ₃ S		metabolism	49829902	7.6% (120 d)	7.6% (120 d)
	MW: 236.63 g/mol SMILES: c1c(sc(n1)Cl)CNC(=O)N[N+](=O)[O-]		Aerobic Aquatic	44715032	36.0% (21 d)	1.6% (365 d)
		0, 0	Metabolism	49589509	8.00% (48 d)	1.10% (100 d)
			Anaerobic Aquatic Metabolism	49589508	7.67% (48 d)	2.47% (100 d)
			Hydrolysis	44703416	35.2% (21 d)	33.3% (30 d)
NOA 459602 (CSCC183497)	IUPAC: Sodium; 5-{5-methyl-4- [nitroimino]-[1,3,5]oxadiazinan-3- ylmethyl}-thiazole-2-sulfonate		Anaerobic soil metabolism	49829901	0.6% (62 d)	ND (153 d)

Code Name/ Synonym	Chemical Name	Chemical Structure	Study Type	MRID	Maximum %AR (day)	Final %AR (study length)
	Formula: C ₈ H ₁₀ N ₅ NaO ₆ S ₂ MW: 359.31 g/mol SMILES: CN\1COCN(/C1=N/[N+](=O)[O-])Cc2cnc(s2)S(=O)(=O)[O-].[Na+]	S S Na ⁺		49829902	4.0% (30 d)	0.5% (120 d)
CGA 265307 (CSAA250354)	IUPAC: N-(2-Chlorothiazol-5-ylmethyl)- N'-nitroguanidine	CI S	Aerobic Soil Metabolism	49589503	5.1% (220 d)	5.1% (220 d)
	CAS No.: 135018-15-4 Formula: C ₅ H ₆ ClN ₅ O ₂ S MW: 235.6 g/mol SMILES: c1c(sc(n1)Cl)CNC(=N)N[N+](=0)[O-]	N H NO 2	Anaerobic Soil Metabolism	49829901	0.3% (120 d)	ND (153 d)
CGA 353968	IUPAC: 1-(2-Chlorothiazol-5-ylmethyl)- 3-methylurea	o 	Soil Photolysis	44715028	1.13 (30 d)	1.13 (30 d)
	Formula: C ₆ H ₈ ClN ₃ OS MW: 205.6 g/mol	s s	Aerobic Soil Metabolism	44703418	3.80 (365 d)	3.80 (365 d)
	SMILES: [H]N(C)C(=O)N([H])Cc1cnc(s1)Cl		Aerobic Aquatic Metabolism	44715032	9.8% (365 d)	9.8% (365 d)
SYN501406 (CSCC188737)	IUPAC: Sodium; 5-(N'-Methyl-N"-nitro-guanidinomethyl)-thiazole-2-sulfonate Formula: C ₆ H ₈ N ₅ NaO ₅ S ₂ MW: 317.27 g/mol SMILES: CN/C(=N/[N+](=O)[O-])/NCc1cnc(s1)S(=O)(=O)[O-].[Na+]	Na *	Anaerobic Soil Metabolism	49829902	2.6% (120 d)	2.6% (120 d)

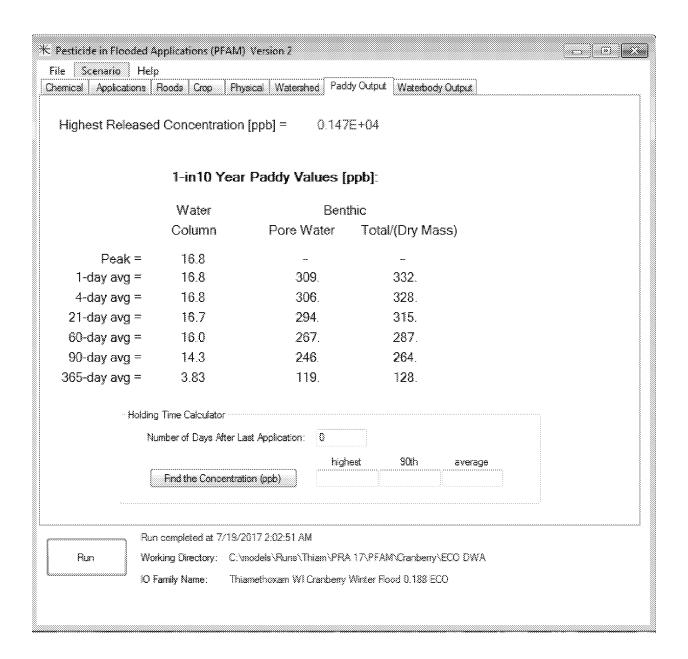
A AR means "applied radioactivity". MW means "molecular weight". PRT means "parent". NA means "not applicable". ND means "not detected

Appendix B. PWC and PFAM Example Outputs for Thiamethoxam.

PWC Output for Surface Water representing Mississippi Cotton - Foliar Application



PFAM Output for Surface Water representing Wisconsin Cranberry – Ground application



PFAM Output for Surface Water representing California Rice – Seed Treatment

